EXHIBIT 2M

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO PLAINTIFFS: **2:12-cv-05201 and 2:12-cv-09972**	

RULE 26 EXPERT REPORT OF PROF. DR. MED. UWE KLINGE

I. TVT AND TVT-O USE THE SAME PROLENE MESH

Attached as Exhibit 1 is a true and correct copy of Dr. Klinge's Rule 26 Expert Report from Lewis 2:12-cv-04301 ("TVT Expert Report") All contents of the TVT Expert Report are hereby incorporated by reference as if fully rewritten herein.

Ethicon uses the exact same Prolene mesh in its TVT and TVT-O incontinence products. Likewise, Ethicon uses the same cutting methods, mechanical cut and laser cut, in manufacturing its mesh products for both TVT and TVT-O. Because the Prolene mesh is the same, all opinions contained in the TVT Expert Report regarding the mesh used in Ethicon's TVT also apply to the mesh used in Ethicon's TVT-O.

February 21, 2014

Prof. Dr. Med. Uwe Klinge

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO PLAINTIFFS: **Carolyn Lewis (2:12-cv-04301)**	

RULE 26 EXPERT REPORT OF PROF. DR. MED. UWE KLINGE

1

I. SUMMARY OF OPINIONS

Based on my background training and experience as a general and abdominal surgeon who used Prolene mesh for hernia repair in patients and treated Prolene-mesh-related complications in patients, and based on 20 years of studying Prolene and other surgical meshes as a biomaterials scientist, ten years of which were as a consultant to Ethicon in their preclinical studies of Prolene and other surgical meshes, performing histopathological analysis on hundreds of explanted hernia, sling and prolapse meshes, being an invited lecturer at conferences around the world on the topic of surgical meshes, authoring or co-authoring over 100 peer-reviewed publications regarding surgical meshes, including numerous ones regarding Prolene mesh, reviewing thousands of pages of scientific literature, thousands of pages of internal Ethicon documents and thousands of pages of deposition testimony, the following is a summary of my opinions in this case, all of which I hold to a reasonable degree of medical and scientific certainty:

The Prolene mesh in TVT undergoes a Chronic FBR.

After implantation of the TVT mesh, there is a chronic (permanent) foreign body reaction in a woman's pelvic tissue whereby the woman's body will react to the polypropylene indefinitely, creating a chronic inflammatory response that leads to scarring around the mesh fibers. Claims by Ethicon in its TVT Instructions for Use (IFU) that "a transient foreign body response may occur" and in its TVT marketing brochures that there is "[n]o foreign body reaction after PROLENE mesh implantation" are inconsistent, false and misleading, and Ethicon knew or

should have been known them to be untrue at the time the company employees wrote these documents and certainly prior to the launch of TVT in 1998.

The Prolene mesh in TVT is a heavy weight mesh ("overengineered").

The greater the surface area of a medical implant, the greater the foreign body reaction and the inflammatory response will be. Ethicon had critical mesh design information regarding the negative consequences in the human tissue of heavy weight, small pore meshes beginning as early as 1998. The heavy weight Prolene mesh (105-110 g/m2) in Ethicon's TVT products is over 10 times stronger than it needs to be for its intended purpose of treating stress urinary incontinence and thus, it is "overengineered" and leaves much more polymer material in a woman's delicate and sensitive pelvic tissues than is necessary. Any pelvic mesh designed with this much excess surface area and weight unreasonably increases the risk of injury to the patient and is a less safe design than lighter weight mesh as it causes an unnecessarily increased FBR and inflammatory response

The Prolene mesh in TVT is a small pore mesh.

The smaller the pores (open space between the fibers) of a mesh implant, the greater the risk of scar tissue forming in the pores ("bridging fibrosis" or "fibrotic bridging") will be. As early as 1998, and certainly by the early 2000's, Ethicon had critical design information that the risk of bridging fibrosis is increased by surgical mesh with pore sizes less than 1mm in all directions, which in turn increases the risk of a rigid scar plate forming throughout the mesh, leading to integration of the entire mesh in scar tissue. Any pelvic mesh designed with pores this small unreasonably increases the risk of injury to the patient and is a less safe design than mesh with pore sizes greater than 1mm in all directions. The pore size of the Prolene mesh in Ethicon's TVT products is, according to Ethicon, less than 1mm.

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Ethicon's failure to implement new, critical mesh design changes (lighter weight, larger pore) in its TVT products before its launch in 1998 was unreasonable, compromised patient safety and has led to patient complications like chronic inflammatory reaction, excessive scarring through and around the mesh, nerve entrapment, chronic pain, dyspareunia, erosions, recurrence and the necessity of reoperation in an attempt to correct these problems. The Prolene mesh in Ethicon's TVT products is unsuitable for use as a permanent implant for treatment of a woman's stress urinary incontinence. Ethicon did not act as a reasonable manufacturer in choosing to use the "Old Construction 6 mil" Prolene mesh in its TVT products.

The Prolene mesh in TVT undergoes pore deformation under minimal load.

A knitted surgical mesh device like the TVT that is permanently implanted in human tissue must be designed in such a manner that the pores of the mesh do not collapse and deform upon the expected forces of implantation as well as the expected in vivo forces. Under minimal strain, the TVT mesh pores deform and collapse thereby increasing the risk of injury to patients in which it is implanted and is a less safe design than products that better withstand these in vivo conditions and do not display these poor outcomes. Permanent deformation and pore collapse of

the TVT mesh leads to fibrotic bridging, scar plate formation, excessive scarring through and around the mesh and a host of tissue complications that can lead to chronic pain, recurrence, erosions, dyspareunia and need for reoperation, to name a few, making it unsafe for its intended purpose of being permanently implanted in a woman's pelvic tissue. As such, Ethicon failed to act as a reasonable manufacturer of surgical mesh intended to treat stress urinary incontinence in women by marketing and selling a product that lacks sufficient stability while undergoing these forces.

The Prolene mesh in TVT contract/shrinks.

The Prolene mesh in Ethicon's TVT products contracts or shrinks 30-50% after implantation. This shrinkage was known to Ethicon prior to the launch of TVT in 1998. TVT mesh shrinkage leads to nerve entrapment and thus, chronic pelvic pain, erosions, urinary/defecatory/sexual dysfunction, recurrence and the need for reoperation to remove some or all of the contracted mesh and excessive scar tissue, thereby making TVT unsuitable for its intended use as a permanent pelvic implant to treat stress urinary incontinence in women. As such, Ethicon failed to act as a reasonable manufacturer of surgical mesh intended to treat stress urinary incontinence in women by failing to design a sling device that would resist such a high level of shrinkage.

The Prolene mesh in TVT degrades/oxidizes.

The Prolene mesh in Ethicon's TVT products is not biologically inert and does in fact undergo degradation of the mesh fiber after implantation in a woman's pelvic tissues leading to an increased host inflammatory response. When the surface area of the mesh increases, so does the inflammatory response. Also, after the surface of the polypropylene fibers degrades and peels off into the surrounding tissue, the body's inflammatory mediators and chemical products associated with the inflammatory process (like peroxides, superoxide and hypochlorous acid) will continue to attack and degrade the underlying polypropylene. This is especially true given that the only two protective anti-oxidants have leached away from the fibers leaving all of the exposed surfaces of the mesh vulnerable to further oxidation/degradation. Claims by Ethicon in its TVT IFU that Prolene mesh is not "subject to degradation…by the action of tissue enzymes is false and misleading" because the Prolene mesh does degrade in the presence of the chemical process inherent in the body's inflammatory reaction to the mesh in the pelvic tissue of women and thus, the TVT products are not suitable for their intended purpose as a permanent prosthetic implant for the treatment of stress urinary incontinence.

3

The Prolene mesh in TVT frays, loses particles, curls and ropes.

The TVT mesh is a knitted textile design without a border and therefore, it has frayed edges that tend to shed particles of polypropylene before, during and after the surgery. As tension is placed on the mesh, it curls, ropes and sheds these particles, all of which make both TVT Mechanical-cut mesh (MCM) and TVT Laser-cut mesh (LCM) unsafe for their intended purpose of being permanently implanted in a woman's pelvic tissues. The frayed edges and the lost, migrating particles of both TVT MCM and TVT LCM as well as the increased stiffness and rigidity of TVT LCM can all lead to increased inflammatory response, chronic foreign body reaction, erosions, chronic pelvic pain, failure of the implant, dyspareunia, organ damage,

urinary dysfunction and the need for surgical intervention. Ethicon failed to act as a reasonable mesh manufacturer by failing to properly design its TVT slings to avoid fraying, particle loss, curling and roping.

The Prolene mesh in TVT causes secondary, mesh-related infections.

The Prolene mesh in Ethicon's TVT products is susceptible to an increased risk of secondary, mesh-related infections as a result of the bacteria that has both adhered to the mesh during the operative procedure and as it is passed through and implanted into a clean/contaminated environment. Ethicon's statements in its TVT IFU that its Prolene mesh used in the TVT products "may potentiate an existing infection" and that the plastic, removable sheath around the sling "is designed to minimize infection" are both inadequate and misleading regarding these secondary, mesh-related infections. Thus, the Prolene mesh in TVT is not suitable for its intended purpose of being implanted permanently in a woman's pelvic tissues, and Ethicon did not act as a reasonable manufacturer by failing to properly study and analyze this critical reality of its Prolene mesh.

The Prolene mesh in TVT does not match the biomechanics of the pelvis.

Once implanted, the TVT mesh will be subjected to various three-dimensional and dynamic forces, stains and stresses. Ethicon had no basis for claiming that its Prolene mesh used in TVT had "bi-directional elasticity" given the anisotropic behavior of its Prolene meshes, nor did Ethicon have a basis for claiming that its Prolene mesh, or any of its mesh for pelvic tissue repair, "allows adaptation to various stresses encountered in the body" when Ethicon admittedly has never properly defined what those stresses are in the pelvis much less how the elasticity of TVT properly adapts to those unknown stresses.

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From the time of the launch of TVT in 1998 until the present, Ethicon has continually lacked sufficient knowledge regarding pelvic floor in vivo forces and has never adequately calculated or estimated such forces through appropriate testing and therefore, it has never designed a pelvic mesh that is adapted to the physiological environment in which it is implanted. This mesh design failure by Ethicon in its prosthetic implants for stress urinary incontinence has led to numerous patient complications and causes the TVT sling to be unsuitable for its intended purpose of being permanently implanted in a woman's pelvic tissue. Ethicon failed to act reasonably in designing their slings without designing the biomechanical/physiological requirements of its intended purpose and its intended environment.

Once implanted, the TVT mesh will be subjected to various three-dimensional and dynamic forces, stains and stresses. Ethicon had no basis for claiming that its Prolene mesh used in TVT had "bi-directional elasticity" given the anisotropic behavior of its Prolene meshes, nor did Ethicon have a basis for claiming that its Prolene mesh, or any of its mesh for pelvic tissue repair, "allows adaptation to various stresses encountered in the body" when Ethicon admittedly has never properly defined what those stresses are in the pelvis much less how the elasticity of TVT properly adapts to those unknown stresses.

There are safer alternative pelvic mesh design characteristics than those of TVT.

There are alternative design characteristics of pelvic floor meshes that would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT.

One such safer alternative design would be a mesh product with larger pores (> 1mm in diameter after accounting for reasonable implantation and in vivo forces) and lighter weight (closer to their Ultrapro mesh which is 25 g/m2). Ethicon has developed a number of meshes for hernia repair and for prolapse repair which are at least closer to fulfilling these requirements. However, even with larger pores and less weight, the knitted structure design would require greater stability, both short and long term, to resist curling, roping, fraying and particle loss. Structural stability under strain and a mesh with finished edges (sealed outer border) would be safer than the Prolene mesh.

Another safer design would be a polymer that better resists degradation and elicits a more favorable inflammatory response. PVDF, as a synthetic, non-absorbable suture or mesh material has improved textile and biological properties over polypropylene. It is thermally stable and more abrasion resistant than other flouroplastics and induces a minimal cellular response, shows exceptional chemical stability and has excellent resistance to aging. Based on these characteristics, my studies comparing PVDF to polypropylene, Ethicon's internal documents and other scientific literature, as well as my background, training and experience over 30 years, PVDF, in the appropriate design, is a safer alternative mesh material for human tissues than Ethicon's TVT Prolene mesh.

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Based upon these facts, I am able to conclude, to a reasonable degree of medical and scientific certainty, that the Prolene mesh used in Ethicon's TVT products is designed in such a way that it does in fact cause a greater inflammatory response and greater foreign body reaction that can, and in some patients does, lead to harmful complications. I am also able to conclude that these materials were inadequately tested and studied and that as a result of all of these factors, set forth more fully in this report, the TVT device is not adequately designed to be safely implanted in a woman's pelvis for the rest of her life.

II. BACKGROUND AND QUALIFICATIONS

With regard to my medical training, I attended medical school in Aachen, Germany from 1977 to 1983. I began my medical profession at the surgical department of the University Hospital of the RWTH, Aachen, Germany (Department heads/Mentors: Prof. Reifferscheid - 1985, Schumpelick 1985-2010, Neumann 2010-). From 1995 to 2006, my practice was focused primarily on abdominal surgery, and specifically, hernia repair. As a hernia surgeon, I used textile implants (flat meshes) for the repair of abdominal wall hernia or defects in more than 300 patients mainly groin hernia, umbilical hernia, incisional hernia and parastomal hernia. Although I never performed surgery for repair of SUI or POP, I implanted and studied the Prolene mesh used in TVT, extensively over many years.

In 1993, in addition to my surgical practice, I began focusing on surgical research in the area of biomaterial science including tissue engineering and material characteristics, and I designed

preclinical models for surgical mesh and histopathology. I am the author/co-author of approximately 200 peer-reviewed publications listed in PubMed, over 100 of which involve hernia and/or surgical mesh. I have authored and/or contributed to more than 50 book chapters and have been an invited lecturer to more than 160 speaking engagements/conferences. I have received numerous research grants from various institutions and corporations including several grants from the German Ministry for Education and Research, the Ministry for Economics, the German research foundation DFG, the NRW Ministry for Education and Research, the Interdisciplinary Center for Clinical Research of the University of Aachen (RWTH), as well as from industry (Ethicon, Covidien). (Attached hereto as Appendix "A" is a current copy of my Curriculum Vitae with a list of my publications).

III. BRIEF HISTORY OF TEXTILE MESHES FOR TISSUE REPAIR 1958-1993 – THE ABDOMINAL WALL

The current use of textile meshes is based on Usher who, in 1958, started to publish the successful reinforcement of the abdominal wall in six dogs. Initially, meshes were regarded as an alternative procedure, particularly in big hernias. In 1986, Lichtenstein presented his procedure of mesh implantation as the new standard for groin hernia repair. With this technique, the mesh reinforces the tissue in a so-called "tension free" manner. In the early years, Usher used a knitted structure of polypropylene, later widely known as Marlex®. However, Marlex® had increased stiffness after implantation along with considerable complications. Alternatives to Marlex were the polyester mesh Mersilene® from Ethicon or the ePTFE mesh from Gore.

In the late 1980's and early 1990's, when polypropylene surgical mesh was increasingly used in hernia surgeries, there was a general lack of knowledge about the materials and about the clinical outcomes associated with these materials. Side effects often manifested with a considerable delay of up to several years. Correspondingly, reports dealing with pain as a major postoperative complication (less than 10% of all hernia publications in PubMed) were published with a delay of years [Fig.1]. We began to look at the scar formation pathologically and developed the theory that incisional hernias could be due to a defective wound healing process with an impaired collagen formation, favoring the necessity to support tissues in these patients by prosthetics.

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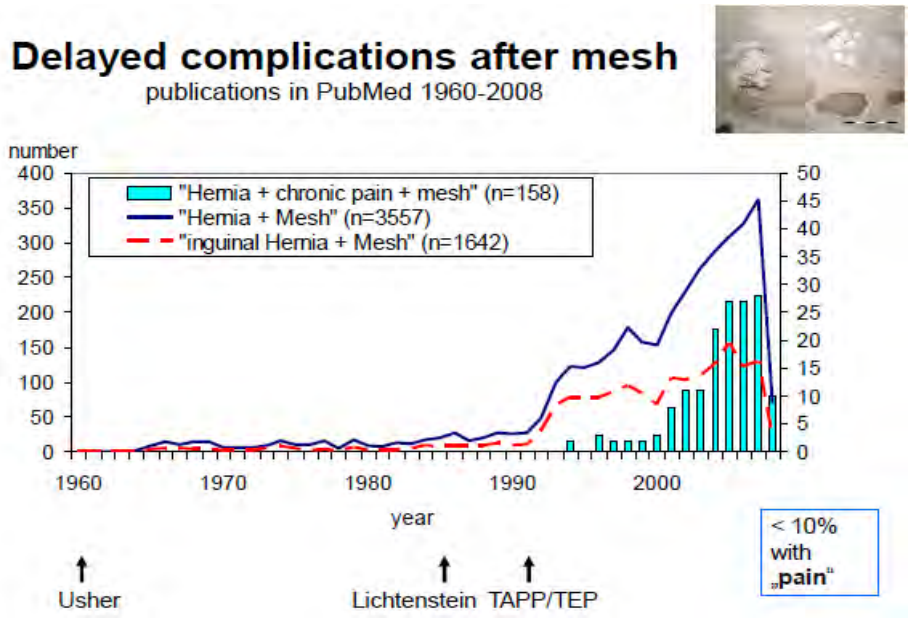

Figure 1

IV. DEVELOPMENT OF THE FIRST LARGE PORE MESH CONSTRUCTION THAT WAS ADAPTED TO PHYSIOLOGICAL REQUIREMENTS

In the early 1990's, we speculated that an adaptation of the strength of surgical meshes to the physiological requirements of the tissues in which they would be implanted may allow a considerable material reduction which could improve biocompatibility. We felt that the textile characterization of meshes at that time did not sufficiently reflect the physicochemical properties of the textile, so we had to start almost from the beginning to first identify the relevant parameters.

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RWTH University initiated a research program such that in conjunction with various grants, we could add some basic investigations to this project. Through cooperative efforts with Ethicon and the support by these research grants, the project went on for about 10 years. In this period, we gained significant knowledge about the textiles; we defined standard biomechanical characterization for better comparison; we established models for testing the tissue response in animals; we looked for parameters that reflected the inflammatory and fibrotic activity of the foreign body reaction; and we developed a technique to quantify the biomechanical impact on, and the biomechanical properties of, tissues.

As our research progressed, we calculated that hernia meshes needed a tensile strength of 16 N/cm and an elasticity of about 20-30% at this strain. Ethicon provided our research team with thin (about 40 µm) polypropylene threads. Because we were provided only with these 40-µm fibers, we had to combine 5 strands of them at interval distances of 2-3 mm to withstand a strain of 16 N/cm. As this polypropylene net was very floppy, we added an absorbable fiber of Vicryl® (Ethicon) to temporarily make it stiffer. After absorption of the Vicryl®, there would remain just an open structure, with about 30% of the material of the Prolene. This new structure with pores larger than 2 mm, later marketed as Vypro® by Ethicon (1998) and patented in 2000 in the US

(6,192,962), was then studied extensively in several experimental studies. The results were presented at several conferences and most of it has been published in PubMed-listed journals. Vypro® was the first truly lightweight, large pore surgical mesh and became the first of the second-generation surgical meshes. This development would become what is known as the "Lightweight Large Pore Concept" which has been adopted by surgical mesh manufacturers worldwide in developing newer generation meshes and was set forth in a publication by my colleagues and me in 2005.[1] Ethicon's own employees have testified that they agree with our work, including that light weight meshes with pore sizes of greater than 1 millimeter in all directions will reduce the foreign body response compared to heavyweight meshes with small pores. Dr. Axel Arnaud, Ethicon's Medical Affairs Group Director, testified that our lightweight large pore concept is "agreed upon by most of the people involved in the science of meshes…this is the basic science about meshes [and] I certainly will not challenge this."[2]

V. BIOCOMPATIBILITY

A. Foreign Body Reaction

All experimental and clinical studies indicate that mesh products on the market today cause an initial and chronic inflammatory tissue response in the recipient after implantation. The quality of the inflammatory reaction to foreign bodies of different natures is surprisingly constant, characterized by a rapid accumulation of huge numbers of phagocytic cells, in particular, blood monocytes and tissue-derived macrophages. This type of inflammatory process is known as a foreign body reaction (FBR). It is characterized by an initial inflammatory burst caused by a release of a huge combination of potent inflammatory mediators which then attract other cell types including T-cells, polymorphonuclear granulocytes (PMNs), plasma cells and fibroblasts. Within a few days, this cellular activity forms an early granuloma layer recognized by the very typical foreign body giant cells and an outer layer of fibrosis with deposition of collagen. This late stage granuloma is not a static type of chronic inflammation but rather, it represents a chronic wound with an increased cell turnover even years after implantation. The various inflammatory cells e.g. macrophages, at the interface and in contact with the polymer, undergo apoptotic cell death and are replaced. [Fig. 2]

8

[1] Klosterhalfen, B., Junge, K., Klinge, U. *The lightweight and large porous mesh concept for hernia repair*. Expert Rev. Med. Devices. 2005; 2(1)
[2] Arnaud deposition 9/25/13 772:25 to 777:16; 779:4-11

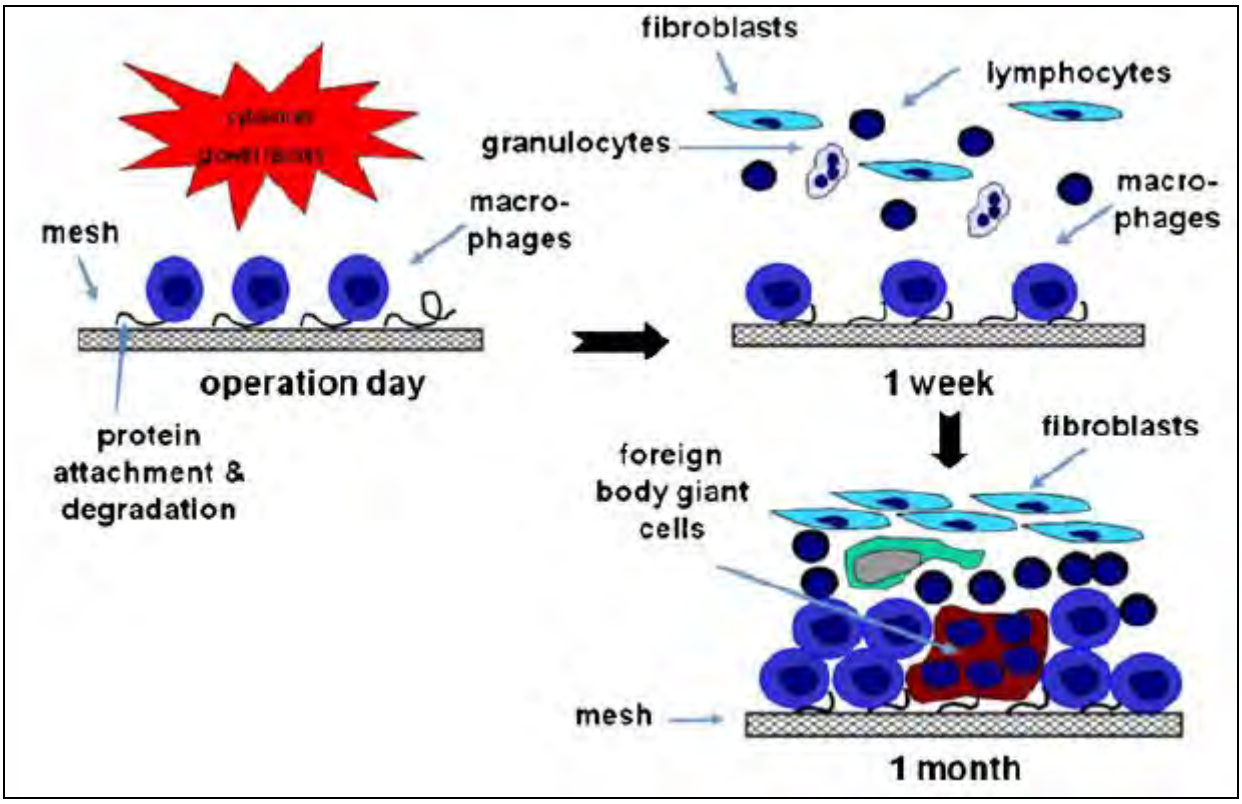

Figure 2[3]

We published our results in 1998 and 1999 of the histological analyses from explanted mesh from rats, dogs and humans. The tissue response in humans was almost identical to the morphological observations in the animal models. In our 1999 study, we reviewed approximately 350 human explant samples of various mesh modifications gathered from centers all over Europe. Even 15 years after explantation, the longest observation in our study, a persistent chronic FBR could still be detected, indicating that mesh is likely never completely inert with respect to local inflammatory processes. The persistence of this FBR is important, especially in younger patients in whom the mesh will remain for several decades. The delay before explantation of mesh for infection of up to 56 months, for chronic pain of up to 48 months and for recurrence of up to 180 months established that in many clinical studies with shorter surveys of less than 1-2 years, the morbidity rates are underestimated.[4,5] It is well known in the medical community that the vagina is to be considered a "clean-contaminated" field. The implantation of mesh may result in a biofilm which will make it difficult for the host cells to kill the mesh infection; in fact, the development of these biofilms will protect the harmful bacteria that the host

[3] Semin Immunopathol (2011) 33:235-243 – Formation of a foreign body granuloma at the mesh to host tissue interface
[4] Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969
[5] Klinge U, Klosterhalfen B, Muller M, Schumpelick V. Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias; Eur J Surg 1998; 164: 951–960

cell set out to kill (See **Bacterial Adherence/Biofilms/Mesh-related Infections** Section below).[6]

Furthermore, my colleague and Ethicon's top pathology consultant for 20 years, Bernd Klosterhalfen, informed Ethicon at an expert meeting at Ethicon's Norderstedt facilities in 2006 that based on our studies, the tissues in the body can react to the mesh for up to 20 years.[7]

At another Ethicon expert meeting at Norderstedt the following year, in a PowerPoint presentation to the experts in attendance, Ethicon stated that there can be "excessive FBR > massive scar plate > more shrinkage" depending on the type of mesh.[8] Ethicon stated in that presentation that "small porous meshes (<1mm) lead to 'fibrotic bridging' > increased shrinkage."

Ethicon employees have testified that Ethicon knew before the launch of its pelvic meshes, for both incontinence and prolapse repair, that in some women, there would be a severe FBR and chronic life-altering inflammatory reaction causing debilitating and chronic pain, erosions, recurrence, need for revision surgery and dyspareunia in some women.[9, 10, 11, 12]

It is my opinion to a reasonable degree of medical and scientific certainty that after implantation of the TVT mesh, there is a chronic (permanent) foreign body reaction in a woman's pelvic tissue whereby the woman's body will react to the polypropylene indefinitely, creating a chronic inflammatory response that leads to scarring around the mesh fibers. Claims by Ethicon in its TVT Instructions for Use (IFU) that "a transient foreign body response may occur" and in its TVT marketing brochures that there is "[n]o foreign body reaction after PROLENE mesh implantation" are inconsistent, false and misleading, and Ethicon knew or should have been known them to be untrue at the time the company employees wrote these documents and certainly prior to the launch of TVT in 1998.[13,14] In addition to abundant scientific literature to the contrary, deposition testimony of numerous Ethicon employees in this litigation also indicates their knowledge of the falsity of this statement.[15,16, 17]

B. Weight

As is evidenced in countless pages of deposition testimony of Ethicon employees and internal Ethicon documents, Ethicon was aware that meshes with lighter weight and larger pores versus the heavy weight, small pore, "Old Construction" TVT Prolene mesh, lessened the risk of these harmful tissue reactions and thus, lessened the risk of injury to patients.

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[6] Osterberg B. ActaChirScand1979;145:431, Merritt K. J BiomatAppl 1991;5:185, An Y. J Biomed Mater Res (Appl Biomat) 1998;43:338
[7] ETH.MESH.00870466 2006 Expert Meeting Norderstedt
[8] ETH.MESH.01782867 "Factors Related to Mesh Shrinkage" Powerpoint presentation by Kestin Spychaj
[9] Hinoul deposition 4/5/12 99:09-99:25, 4/6/12 518:14-520:20, 6/26/13 175:1-176:17, 184:18-22 328:10-24;
[10] Owens deposition 9/12/2012 98:11to 99:07;
[11] Batke deposition 08/01/13 257:23 to 259:13
[12] Arnaud deposition 9/25/13 769:23 to 770:4
[13] ETH.MESH.00339437-442 "5 Years of Proven Performance" Feb 2002
[14] ETH.MESH.02340504 TVT IFU
[15] Barbolt deposition 10/9/13 137:01 to 137:17;
[16] Holste deposition 07/29/13, 51:3 to 53:6
[17] Hellhammer deposition 9/11/2013, 60:24-61:1; 210:15-211:16

Ethicon's Medical Affairs Director, Piet Hinoul, recounts the history of Ethicon's attempts to develop lighter weight, larger pore meshes and the multiple reasons for doing so in a 2012 Clinical Expert Report for their light weight, large pore mesh, Ultrapro/Prolift + M:[18]

> Knitted, polypropylene mesh as a reinforcement for Hernia Repair has been used for 40+ years and is an accepted method for reducing recurrence of abdominal wall defects seen in both incisional and inguinal hernias. However, implantation of polypropylene mesh is associated with an increase in problems associated with the foreign material implant. Complications associated with these materials have led to changes in implant materials and construction with a goal to 1) reduce implant mass and 2) increase the mesh pore size. The impact of such reductions in material mass on the durability of the repair must be considered. Assessing the breaking strength of healthy tissue, in vivo measurements of maximum pressure during the stresses of coughing, jumping and Valsalva maneuver, and mathematical modeling of abdominal wall forces, have led to the conclusion that synthetic mesh implants, even the lower mass mesh implants, are significantly stronger than required (Deprest et 2006, Cobb et al. 2005).[19]

The Cobb 2005 article states that heavy weight meshes with pores of 800 microns or smaller lead to bridging across the pores ("fibrotic bridging"). He lists several meshes of varying weights in the article of which Prolene is one of the heavyweight meshes. [See Figures 1 and 2][20]

[18] ETH.MESH.08315779 "Clinical Expert Report" dtd 9-25-2012 at 782.
[19] ETH.MESH.08315779 "Clinical Expert Report" dtd 9-25-2012 at 782.
[20] Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7

Table 1. Polypropylene meshes of differing densities

Surgipro[a]	110 g/m^2
Prolene[b]	105 g/m^2
Marlex[c]	95 g/m^2
Prolite[d]	90 g/m^2
Prolene Soft Mesh[b]	45 g/m^2
Vypro II[b]	35 g/m^2
Ultrapro[b]	28 g/m^2

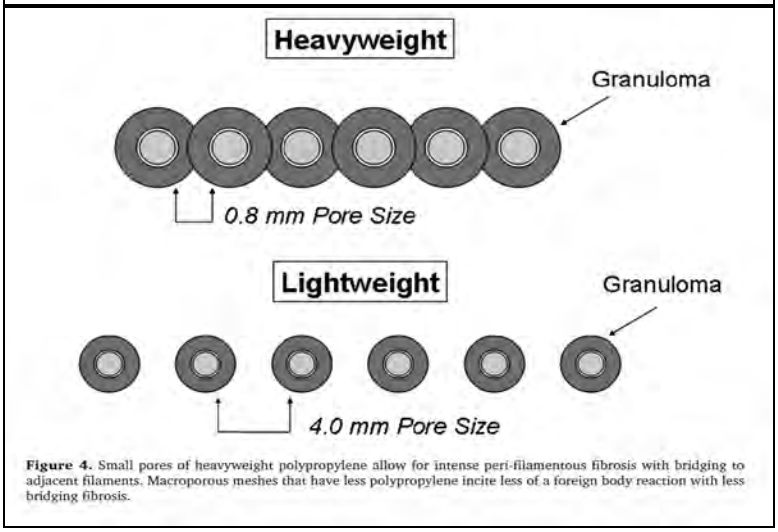

Figure 4. Small pores of heavyweight polypropylene allow for intense peri-filamentous fibrosis with bridging to adjacent filaments. Macroporous meshes that have less polypropylene incite less of a foreign body reaction with less bridging fibrosis.

Figures 1 and 2

It is my opinion, to a reasonable degree of medical and scientific certainty, that the greater the surface area of a medical implant, the greater the foreign body reaction and the inflammatory response will be. Ethicon had critical mesh design information regarding the negative consequences in the human tissue of heavy weight, small pore meshes beginning as early as 1998. The heavy weight Prolene mesh (105-110 g/m2) in Ethicon's TVT products is over 10 times stronger than it needs to be for its intended purpose of treating stress urinary incontinence and thus, it is "overengineered" and leaves much more polymer material in a woman's delicate and sensitive pelvic tissues than is necessary. Any pelvic mesh designed with this much excess surface area and weight unreasonably increases the risk of injury to the patient and is a less safe design than lighter weight mesh as it causes an unnecessarily increased FBR and inflammatory response

C. Pore Size

Polypropylene filaments cause an intense inflammatory response in the abdominal wall as well as in the tissues of the pelvic floor. There is an increased fibrotic reaction hindering the physiological remodeling at the tissue/implant interface. This intense scar formation contributes to the wound contraction.[21]

In our studies from the late 1990's, in which we evaluated the inflammatory response and fibrotic reaction in the tissues at the interface with the mesh implant, we saw that that large pore mesh (Vypro) was integrated into a loose network of perifilamentous fibrosis with fat tissue present in between the fibers. In contrast, the small pore mesh was incorporated entirely in perifilamentary granulomas and scar tissue, which bridged the whole pore diameter <1 mm. This phenomenon, known as "fibrotic bridging", exists when granulomas, side by side, form a common outer fibrotic capsule joining each mesh fiber and forming a rigid "scar plate" covering the whole mesh. This scar plate leaves no space for further tissue ingrowth and leads to a number of complications including loss of elasticity and pain associated with the rigidity, shrinkage or contraction of the mesh, mesh erosion, nerve entrapment, bacterial encasement, chronic pain and dyspareunia.

The concept of fibrotic bridging was and is well known to Ethicon and is evident in numerous internal Ethicon documents. [22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34] [Figure 3]

[21] Junge K., Binnebosel, M., Rosch R., Jansen, M., Kammer,, D., Otto, J., Schumpelick, V., Klinge, U., *Adhesion formation of a polyvinylidenflouride/polypropylene mesh for intra-abdominal placement in a rodent animal model*. (2009) Surg Endosc; 23(2):327-33
[22] ETH.MESH.04037600 Innovations in mesh development
[23] ETH.MESH.05920616 7/20/07; Chomiak, Martin to Batke, Boris; Jamieson, Gillian; Koehler, Petra; Hellhammer, Dr. Brigitte SUBJECT: Defining light weight mesh
[24] ETH.MESH.05585033
[25] ETH.MESH.05446127 3/13/2006 Holste, Dr. Joerg to Engel, Dr. Dieter; Manley, Quentin; Storch, Mark L. SUBJECT: AW: Mesh and Tissue Contraction in Animal
[26] ETH.MESH.05475773
[27] ETH.MESH.04015102 3/01/12 Batke, Boris to Mayes, Casey SUBJECT: AW: AGES Pelvic Floor Conference-Gala Dinner Invitation
[28] ETH.MESH.04037600 Mesh Innovations PowerPoint
[29] ETH.MESH.09651393 Invention Disclosure
[30] ETH.MESH.05585066 "Ultrapro" Powerpoint presentation by Boris Batke
[31] ETH.MESH.05916450 "Chronic Pain Prevention/future – Bioengineer's point of view"
[32] ETH.MESH.04037600 "Innovations in Mesh Development" PowerPoint presentation by Boris Batke
[33] ETH.MESH.00237968 "R&D Perspective – The Journey from Prolift to Prolift +M" PowePoint presentation by Cliff Volpe
[34] ETH.MESH.01782867 "Factors Related to Mesh Shrinkage" by Kerstin Spychaj

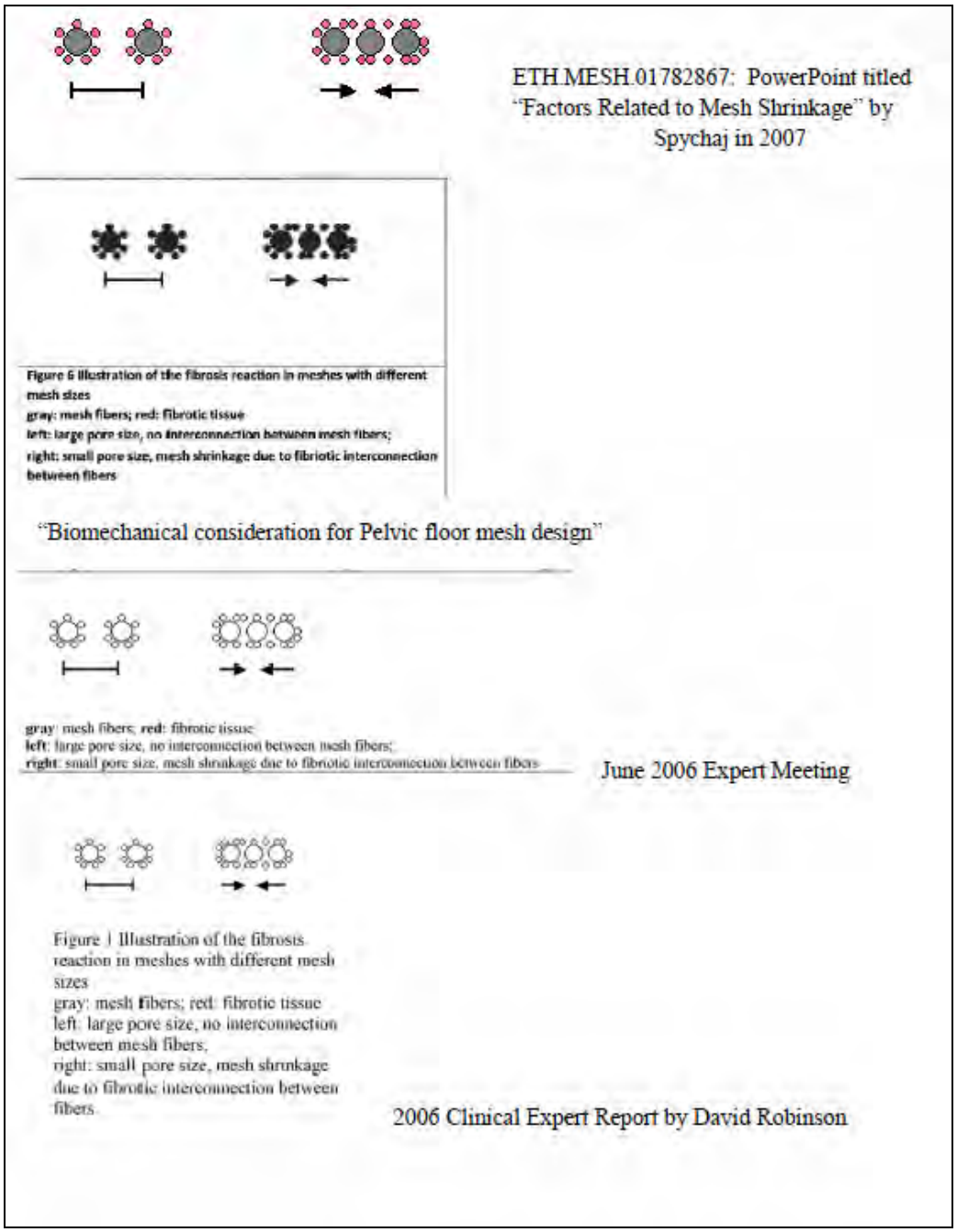

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Figure 3

With the development of Vypro, we were able to increase the pore size by up to 500-600% (Vypro 3-5 mm vs. Prolene <1mm) and decreased the weight from 105-110 g/m^2 (Prolene) to 25g/m^2 (Vypro). Given that the risk of bridging fibrosis is increased by mesh with pore size < 1mm in all directions, any mesh designed with pores this small increases the risk of injury to the patient and is a less safe design than mesh with pore sizes > 1mm in all directions. Simply put:

the greater the pore size or open space in between fibers, the less the risk of fibrotic bridging and formation of a rigid and potentially dangerous scar plate encapsulating the mesh. Again, Ethicon had this critical mesh design information regarding the consequences in the human tissue of heavy weight, small pore meshes beginning as early as 1998, and this is evident in numerous depositions of Ethicon scientists.[35, 36, 37, 38, 39][Figure 4]

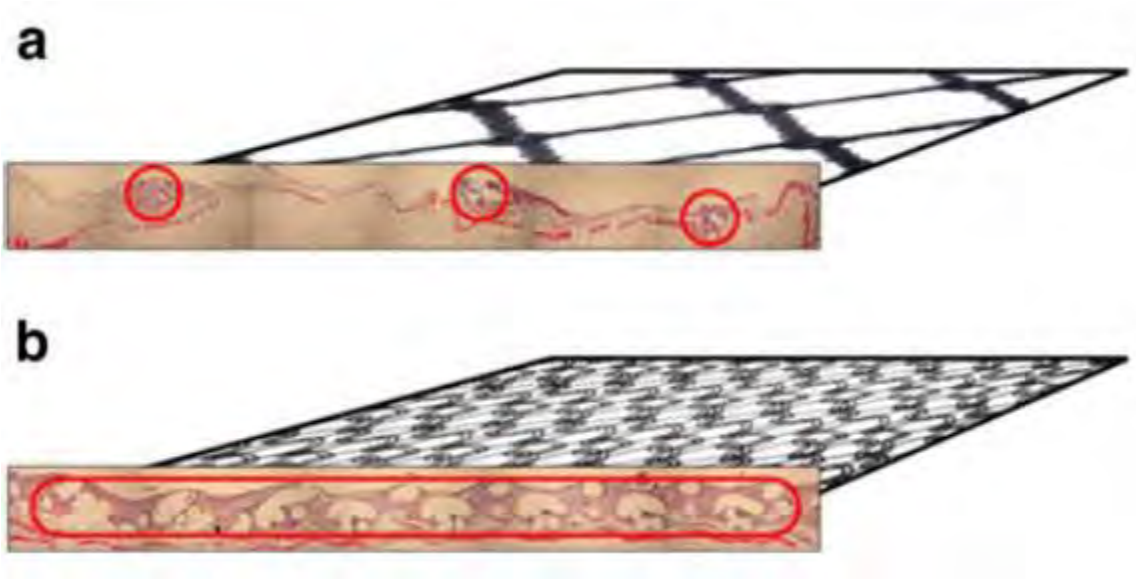

Figure 4

A rather infamous DVD produced by Ethicon and featuring an Ethicon consultant and fellow hernia surgeon, Dr. Todd Heniford, was shown at conferences and seminars in the late 2000's. Ethicon was involved in the production of that DVD as evidenced by the cover of the DVD and their name at the end of it.[40] That DVD touts the benefits of lightweight, large pore meshes and, importantly, describes the dangers of heavy weight, small pore meshes.[41] Dr. Heniford uses slides in the DVD that are from his published literature with his colleague, Dr. William Cobb that has been referenced in numerous Ethicon documents, PowerPoint presentations, professional education materials, expert meetings and Clinical Expert Reports.[42, 43, 44, 45]

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[35] Batke deposition 08/01/012 113:3 to 114:3, 172:6 to 174:15, 118:10 to 120:25
[36] Hellhammer deposition 09/12/13 403:18 to 404:9; 407:13-23
[37] Holste depositions 07/29/13 51:3 to 53:6; Holste Deposition 12/14/12 89:20 to90:21
[38] Semin Immunopathol (2011) 33:235–243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation
[39] Arnaud deposition 9/25/13 756:9 to 757:8
[40] B. Todd Heniford 2007 "The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair" Cover
[41] B. Todd Heniford 2007 "The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair" Video
[42] ETH-47802 Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW, Heniford BT *Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model*.J Surg Res. 2006 Nov;136(1):1-7. Epub 2006 Sep 22.;
[43] ETH.MESH.01424029 Cobb W, Kercher K, Heniford T. *The Argument for Lightweight Polyropylene Mesh in Hernia Repair*. Surgical Innovation. 2005; 12(1):T1-T7;

At one point in the DVD, published with an Ethicon/JNJ logo from 2007, Dr. Heniford states that with the advent of lightweight, large pore meshes "there really is not a reason to use heavyweight polypropylene in the human body…to say well this is the mesh I've always used is not an excuse to continue to use it." ". Ethicon internal documents by Joerg Holste and Boris Batke indicate Ethicon's knowledge of this DVD and were concerned that Prolene is very similar to the Marlex listed in the DVD.[46, 47]

In the work of Dr. Cobb, the weight of TVT Prolene is listed as the heaviest weighted mesh. Ethicon cites to this work repeatedly. The Prolene mesh in TVT was first marketed in 1974 and as such, is Ethicon's oldest, heaviest weight, smallest pore mesh yet to this day; Ethicon continues to sell it in all of their currently-marketed TVT products. In their depositions, Ethicon employees have acknowledged that they knew that the heavy weight, small pore mesh in TVT Prolene mesh can lead to an increased risk of a greater FBR, more intense and chronic inflammatory response, shrinkage or contraction of the mesh, nerve entrapment in the pelvic tissues, erosions and chronic pelvic pain.[48, 49, 50]

Ethicon has used its "Old Construction" 6 mil Prolene hernia mesh (first marketed in 1974) in all of its TVT meshes since the original TVT was launched in 1998.[51] Axel Arnaud, the Medical Director of Ethicon France acknowledged that the Prolene mesh used in TVT products has never changed.[52] It is my opinion, to a reasonable degree of medical and scientific certainty, that the "Old Construction" 6 mil Prolene hernia mesh in Ethicon's TVT products is heavy weight, small pore (<1mm in diameter) mesh which causes a greater FBR and more intense inflammatory response in human tissues than lighter weight, larger pore meshes, making it more susceptible to fibrotic bridging, scar plate formation and encapsulation of the mesh in scar tissue leading to a cascade of harmful reactions in human tissue, including pelvic tissues.

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A number of Ethicon employees have testified that they became aware of the lightweight large pore concept by 1998 through Ethicon's collaboration with both Dr. Bernd Klosterhalfen and me during the development of Vypro. [53] Numerous Ethicon internal documents demonstrate the Ethicon was acutely aware of the heavyweight, small pore problem. [54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64,

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[44] ETH.MESH.08315779 Piet Hinoul Clinical Expert Report Gynecare Prolift +M Pelvic Floor Repair;
[45] ETH.MESH.00237968 "R&D Perspective - The Journey from Prolift to Prolift +M" Powerpoint by Cliff Volpe
[46] ETH.MESH.05479411 Heavyweight to Lightweight Meshes PowerPoint
[47] ETH.MESH.05918776 2004 email re Marlex Experience
[48] Batke deposition 08/01/13 87:12 to 88:10, 113:3 to 114:3, 257:23 to 259:13
[49] Holste deposition 07/29/13 51:3 to 53:6, 55:22 to 57:4
[50] Vailhe deposition 6/20/13 182:2 to 185:5
[51] Holste deposition 7/29/2013 38:21 to 40:15; Batke deposition 08/01/2013 103:11 to104:21
[52] Arnaud deposition 07/19/2013 37:7 to 40:10
[53] Batke deposition 08/01/12, 113:3 to 114:3, 172:6 to 174:15, 118:10 to 120:25; Hellhammer deposition 09/11/13 57:16 to 59:16; Hellhammer deposition 09/12/13 550:1 to550:14; Holste depositions 07/29/13, 51:3 to 53:6; Holste Deposition 12/14/12, 89:20-90:21; Arnaud deposition 09/25/13 756:9 to 756:19
[54] ETH.MESH.04037600 Innovations in mesh development ETH.MESH.01782867 "Factors Related to Mesh Shrinkage" by Kerstin Spychaj
[55] ETH.MESH.05920616 7/20/07; Chomiak, Martin to Batke, Boris; Jamieson, Gillian; Koehler, Petra; Hellhammer, Dr. Brigitte SUBJECT: Defining light weight mesh
[56] ETH.MESH.05585033
[57] ETH.MESH.05446127 3/13/2006 Holste, Dr. Joerg to Engel, Dr. Dieter; Manley, Quentin; Storch, Mark L. SUBJECT: AW: Mesh and Tissue Contraction in Animal
[58] ETH.MESH.05475773

[65,66] Ethicon employees have also admitted that the Prolene mesh used in TVT products was heavyweight and small pore mesh. [67, 68]

A decision was apparently made in 1998 to change the TVT Prolene mesh construction. In 1998, Ethicon indicated that its "long-term desire [was] to support the PHS and TVT devices with **the new construction material**."[69] [Emphasis added] Ethicon seemingly planned from the time of the launch of TVT to replace the "Old Construction 6 mil" mesh with a new mesh construction; however, they delayed making these improvements for the purpose of getting the TVT device on the market in Europe by October 30, 1997:

> Product's improvements
> **In order to meet our objective and launch TVT on October 30th, 1997, we decided to simplify our activity both at manufacturing and development level.**
> As we have moved ahead in our European activity, we have in fact realised that product
> improvement is not a major issue in Europe.
> **Anyhow, we recognise that some amendments are desirable and therefore are going to work on a second generation product to be released 1 Q99.**
> **Following changes will be made:**
> **• new construction Prolene* mesh to be used (after clinical test by Prof. Ulmsten and Prof. Nilsson**
> - 40 patients with 6 moths follow-up)
> • 5 mm needles instead of 6 mm (width)
> • shiny surface of needles (instead of opaque) to provide "slim" effect
> • new shrinking tube (transparent) for needle-tape swaging
> • blister pack
> **Manufacturing and operations will be followed up during 1998, so as to ensure release of second generation product 1 Q99.** [70] [Emphasis added]

Unfortunately for patients, Ethicon chose not to replace its "Old Construction 6 mil" Prolene mesh in its TVT products but rather, chose to use the same mesh they had been marketing since 1974, without regard to critical design developments and considerations that they had studied, developed and were ready to launch.

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[59] ETH.MESH.04015102 3/01/12 Batke, Boris to Mayes, Casey SUBJECT: AW: AGES Pelvic Floor Conference-Gala Dinner Invitation
[60] ETH.MESH.04037600 Mesh Innovations PowerPoint
[61] ETH.MESH.09651393 Invention Disclosure;
[62] ETH.MESH.05585066 "Ultrapro" Powerpoint presentation by Boris Batke;
[63] ETH.MESH.05916450 "Chronic Pain Prevention/future – Bioengineer's point of view"
[64] ETH.MESH.04037600 "Innovations in Mesh Development" PowerPoint presentation by Boris Batke;
[65] ETH.MESH.00237968 "R&D Perspective – The Journey from Prolift to Prolift +M" PowePoint presentation by Cliff Volpe;
[66] ETH.MESH.01203957 The Future of surgical meshes: the industry's perspective PowerPoint by Piet Hinoul
[67] Hellhammer deposition 09/12/13 550:1-14
[68] ETH.MESH.05479535
[69] ETH.MESH.09264884
[70] ETH.MESH.10183005

It is my opinion, to a reasonable degree of medical and scientific certainty that the smaller the pores (open space between the fibers) of a mesh implant, the greater the risk of scar tissue forming in the pores ("bridging fibrosis" or "fibrotic bridging") will be. As early as 1998, and certainly by the early 2000's, Ethicon had critical design information that the risk of bridging fibrosis is increased by surgical mesh with pore size less than 1mm in all directions, which in turn increases the risk of a rigid scar plate forming throughout the mesh, leading to integration of the entire mesh in scar tissue. Any pelvic mesh designed with pores this small unreasonably increases the risk of injury to the patient and is a less safe design than mesh with pore sizes greater than 1mm in all directions. The pore size of the Prolene mesh in Ethicon's TVT products is, according to Ethicon, less than 1mm.

It is also my opinion, to a reasonable degree of medical and scientific certainty, that Ethicon's failure to implement new, critical mesh design changes (lighter weight, larger pore) in its TVT products before its launch in 1998 was unreasonable, compromised patient safety and has led to patient complications like chronic inflammatory reaction, excessive scarring through and around the mesh, nerve entrapment, chronic pain, dyspareunia, erosions, recurrence and the necessity of reoperation in an attempt to correct these problems. The Prolene mesh in Ethicon's TVT products is unsuitable for use as a permanent implant for treatment of a woman's stress urinary incontinence. Ethicon did not act as a reasonable manufacturer in choosing to use the "Old Construction 6 mil" Prolene mesh in its TVT products.

D. Pore Deformation

In approximately 2005, I applied for and received a grant to study the porosity of textile meshes in an attempt to objectify porosity in a reproducible manner. Working with an engineer at the FH Aachen University of Applied Sciences, Prof Thomas Muehl, we published the results of this granted project in 2008 in the Journal of Biomedical Materials Research Part B: Applied Biomaterials.[71]

Our research was based on my research since the late 1990's that pore sizes that prevent fibrotic bridging and will permit ingrowth of physiological tissues should exceed 1 mm between two polypropylene filaments. As stated in our publication, "To exclude large pore areas that may be provided by long and thin pores with narrow parts of pores, the pore geometry has to be evaluated as well. Therefore, only those pores and those parts of the pores are extracted, which have dimensions greater than 1mm or 1000 μm in all directions. The remaining porosity is defined as 'effective porosity'".

We published another study of the pore size/porosity of surgical meshes in 2013 based on our 2008 work which studied and analyzed Ethicon's Prolift and Prolift +M pelvic organ prolapse meshes. [72]

[71] Muehl T, Binnebosel M, Klinge U, Goedderz T. New Objective Measurement to Characterize the Porosity of Textile Implants. J Biomed Mater Res Part B: Appl Biomater. 2007; 84B:176-183

[72] J. Otto, et al., Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation of scar plates; J Biomed Mater Res A 2013 Apr 29

In connection with this litigation, Prof. Muehl has performed similar testing on Ethicon's surgical mesh products using the same porosity test methods as we used in our studies in 2008 and 2013.[73] (NOTE: An Ethicon R&D Scientist, Vincenza Zaddem, Team Leader of Prolift +M and Technical Lead of Prolift, was shown the Muehl study from 2007 and she testified that it sounded like a valid test and that she believed that it would be a good test for Ethicon to look into in order to determine the effective porosity and effective porosity under strain of their pelvic meshes.[74]) This was again confirmed in testimony by Ethicon employee, Joerg Holste and circulated numerous times within Ethicon as a "more sophisticated set up" than Ethicon's method of porosity testing. [75, 76, 77] Ethicon was also aware of the concept of "effective porosity" and the necessity of maintaining pore sizes of >1mm after stretch.[78, 79, 80, 81, 82, 83] [Figure 5]

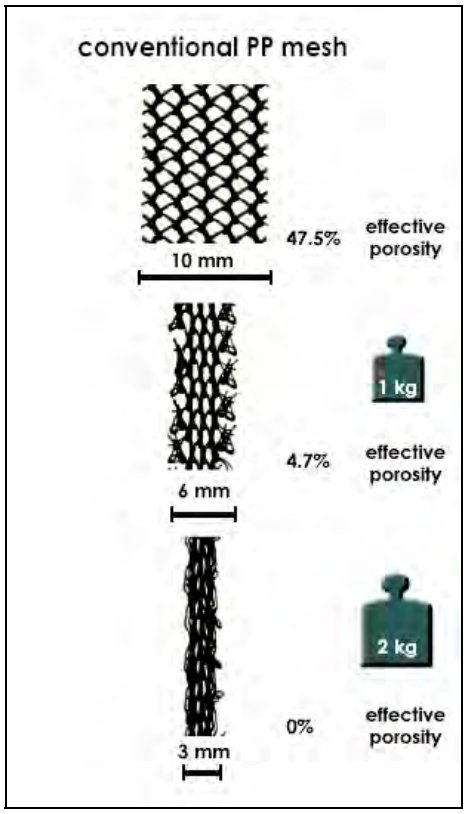

Figure 5[84]

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[73] Prof. Thomas Muhl Report
[74] Zaddem deposition 03/28/12, 387:14 to 387:20
[75] Holste deposition 10/9/2013, 417:9 to 418:22
[76] ETH.MESH.02184130 2008 email circulating New Objective to Characterize the Porosity of Textile Implants
[77] ETH.MESH.04945136 2010 email circulating New Objective to Characterize the Porosity of Textile Implants
[78] ETH.MESH.03021946 T-Pro Stage Gate Meeting on August 25, 2008
[79] ETH.MESH.02587926 When the Implant Worries the Body
[80] ETH.MESH.01752532: Mesh Design Argumentation Issues
[81] ETH.MESH.01785259 January 17, 2010 Email re; +M relaxation
[82] ETH.MESH.02587925 "When the implant worries the body" PowerPoint presentation
[83] ETH.MESH.02185582 "Biomechanical Considerations for Pelvic Floor Mesh"
[84] ETH.MESH.03021946 T-Pro Stage Gate Meeting 8/25/08

Ethicon estimates that its TVT slings will encounter elongation or stretch once placed in a woman's body to 20%.[85] In other Ethicon internal documents, Ethicon estimates the in vivo forces placed on its TVT slings will be approximately 1N.[86] In other Ethicon documents, Ethicon scientists quote the intra-abdominal pressures as follows: [87]

- Standing: 23cm H_2O
- Lifting 5kg: 22 cm H_2O
- Valsalva: 79 cm H_2O
- Coughing: 96 cm H_2O
- Bearing down: 102 cm H_2O

Moalli et al. cited our published work in 1999 that "forces applied to mid-urethral slings in vivo is estimated to be in the range of approximately 5 to 15 N or 1.1 to 3.4 lbs." [88]

When developing the protocol for testing the TVT meshes, I determined the uniaxial forces that would be placed on the mesh as following assumptions:

- In contrast to flat meshes without tensile stress, narrow slings may be considered to work as ligaments having to withstand uniaxial strain.[89] This is undisputable for the process of implantation and the early postoperative time. To mimic the mechanical strain in this phase, we applied strain to the mesh in an uniaxial setting;

- The strain applied should cover the forces and the elongation that can be assumed to be relevant;

- Forces were related to the width of the sling, and thus N/cm was used for comparison with estimated membrane tensions;

- Membrane tension of 16 N/cm was calculated as requirement for the abdominal wall. As the diameter of the pelvis is less than a half of the abdominal wall, the membrane tension should be less than half; [90]

- Experimental studies by DePrest et al resulted in a membrane tension of 2 to 5 N/cm as strain to be expected in the pelvic floor, 1 N/cm in non-prolapsed tissues;

- The tensile strain in the pelvic floor is expected to lead to an elongation of the textile. An elongation of up to 20% is considered to form the comfort zone, and elongation of 40% defines the safety zone; [91]

[85] ETH.MESH.00541379 Memo to File from Martin Weisberg re: Mesh Fraying to TVT Devices
[86] ETH.MESH.00584491 2006 email re AFNOR standards; ETH.MESH.01219414: Elongation Characteristic of Laser Cut PROLENE Mesh for TVT; Smith deposition 08/21/2013, 587:22 to 588:23
[87] ETH.MESH.05237872 "Mesh Properties – How important are they?" by Peter Meier
[88] Moalli P., Papas, N., Menefee S., Albo, M., Meyn, L., Abramowitch, D., Tensile properties of five commonly used mid-urethral slings relative to TVT *Int Urogynecol J* (2008) 19:665-633
[89] ETH.MESH.04048515 at 8518: KOL Interview of Carl G. Nilsson
[90] ETH.MESH.02010834 "Biomechanical consideration for Pelvic floor mesh design" by Juergen Trzewik and Christoph Vailhe; ETH.MESH.04048515 Nilsson KOL interview; Trzewik deposition 09/18/2013 226:20-22; ETH.MESH.02227224 Thunder PowerPoint 05/09/2008

· The tensile force during implantation procedure of a pelvic mesh is considered to be up to 30 N, [92] andcorrespondingly, the in vitro simulation should have less tensile strength;

· The intra-abdominal pressure to the pelvis is estimated by Janda to be 8.3 kPa, whereas an intra-abdominal pressure of 20 kPA is estimated to stress the abdominal wall to 16 N/cm - a lower intra-abdominal pressure leads to a lower tensile load. Considering the lower diameter of the pelvis, a mechanical load of less than 10 N/cm would be reasonable; [93]

· Pullout force is considered by Ethicon to be 1.6 N/cm (20% elongation; 164g = “physiological” load); [94]

As a consequence, although the burst strength of Prolene is 91 N/cm (REF Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Klosterhalfen B, Klinge U, Schumpelick V. Biomaterials. 1998 Dec;19(24):2235-46.]

We applied forces of 1 to 10 N to the slings, which should cover an elongation of less than 40%; altogether, a range that is used in internal studies of Ethicon as well.[95]

Ethicon’s biomechanical engineer, Juergen Trzewik’s “Invention Disclosure” helped to further define our porosity testing parameters and protocols. **[96]** In his Invention Disclosure, Dr. Trzewik wrote:

> The physiological, mechanical boundary conditions can be separated into two main conditions. The comfort zone is defined by the load situation within the implant under normal physiological conditions.
>
> **Here, 'the main load of 2,5 kPa is delivered by the weight of internal organs 2,5 kPa**
>
> *[1] S.Janda,"Biomechanics of the pelvic floor musculature."TU Delft, 2006.[2] K.K.O'Dell, A.N.Morse, S.L.Crawford, and A.Howard,"Vaginal pressure during lifting, floor exercises, jogging, and use of hydraulic exercise machines," Int. Urogynecol. J. Pelvic. Floor. Dysfunct., vol. 18, no. 12, pp. 1481-1489, Dec.2007.*
>
> **The material of the implant basic structure is designed to be characterized by a comfort zone of high elasticity at a low physiological load**

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[91] ETH.MESH.02010834 "Biomechanical consideration for Pelvic floor mesh design" by Juergen Trzewik and Christoph Vailhe
[92] ETH.MESH.02588182

[93] ETH.MESH.04006021; ETH.MESH.02185596
[94] ETH.MESH.03658927
[95] Moalli P, Papas N, Menefee S, Albo M, Meyn L, Abramowitch D; Tensile properties of five commonly used mid-urethral slings relative to TVT. Int Urogynecol J (2008) 19:655-663
[96] ETH.MESH.09651393 Invention Disclosure

and a safety zone characterized by low elasticity at high loads. Both zones are separated by the construction of the yield point by tangential approximation of the stress strain curve for the zone of initial elongation and the slope of region of high stress. The yield point for vaginal tissue is considered to be between 10%-200% of area strain.

[1]C.Rubod,M.Boukerrou,M.Brieu,P.Dubois,andM.Cosson,"Biomechanicalpropertiesofvaginaltissue.Part1: new experimental protocol," J. Urol., vol. 178, no. 1, pp. 320-325, July2007.[2]H.Yamada,StrenghtofBiologicalMaterials.Baltimore:TheWiliams&WiliamsCompany,1970.

The stretch of vaginal tissue may exceed 300 % under certain conditions.

[3]J.M.Miller,D.Perucchini,L.T.Carchidi,J.O.DeLancey,andJ.Ashton-Miller,"Pelvicfloormusclecontractionduringa cough and decreased vesical neck mobility," Obstet. Gynecol., vol. 97, no. 2, pp. 255-260, Feb.2001.

The yield point is individually defined for the different structures of the implant (e.g., the arms of the implant are characterized with a lower yield point than the implant body).The material behaviour simulates the behaviour of tendon structures is described by a significantly reduced elasticity compared to the implant body *.[H. Yamada, Strength of Biological Materials. Baltimore: The Wiliams & Wiliams Company, 1970]* **The yield point for the arms should not exceed 10 %.**

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The implant material is anisotropic and stretches differently in longitudinal and transversal direction. The yield point in the transversal direction exceeds the longitudinal direction between 100%-500%.

[1]C.Rubod,M.Boukerrou,M.Brieu,P.Dubois,andM.Cosson,"Biomechanicalpropertiesofvaginaltissue.Part1: new experimental protocol," J. Urol., vol. 178, no. 1, pp.320-325, July2007.[2] H. Yamada, Strength of Biological Materials. Baltimore:The Wiliams & Wiliams Company, 1970.

Biomechanical features like increased flexibility are undesired during the surgical procedure of implant placement, to avoid any uncontrolled or undefined stretching of the implant during implantation. Pre- straining of the implant would change the mechanical properties of the implant. A temporary stress- shielding of the long-term implant is necessary during implantation and wound contraction.

[Y.Abramov,A. R. Webb, J. J. Miller,A. Alshahrour, S. M. Botros,R. P. Goldberg ,G. A. Ameer ,and P .K. Sand ,"Biomechanical characterization of vaginal versus abdominal surgical wound healing in the rabbit,"Am. J. Obstet. Gynecol., vol. 194, no. 5, pp. 1472-1477, May2006]

The yield point of the implant is lower than <10% before absorption of the supporting stress shielding structure.

As a consequence of all this information, we performed measurements to 11 mm TVT and TVT-O slings at a strain of

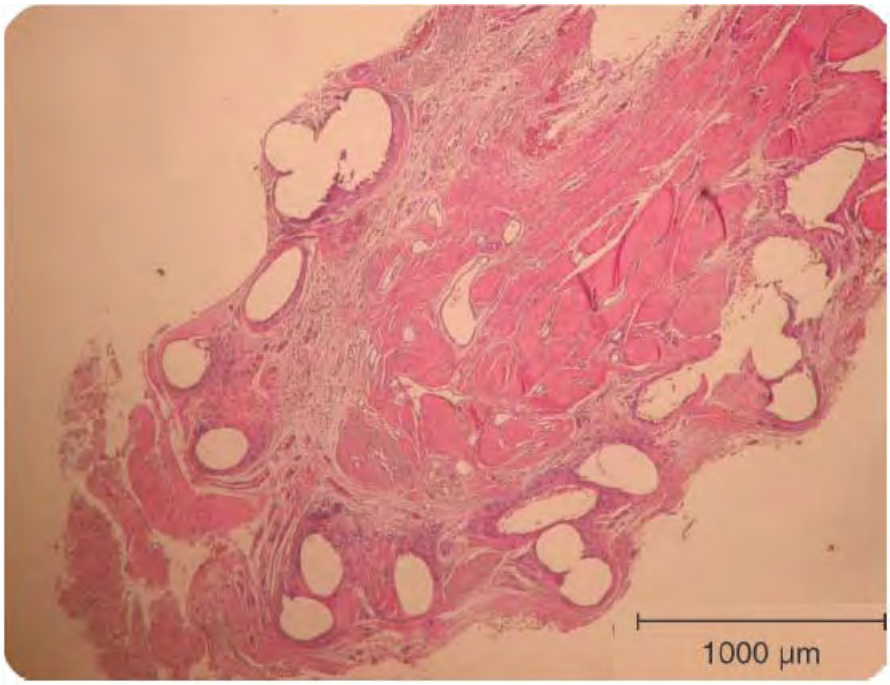
- 102 g (0.9 N/cm)
- 164 g (1.5 N/cm)
- 250 g (2.2 N/cm)
- 500 g (4.5 N/cm)
- 1000 g (8.9 N/cm)

The significance of the Muehl method of testing these mesh products is that it provides useful data in terms of how a mesh will perform in the human body, particularly in regard to the risk of fibrotic bridging. The first most important observation from this testing was that the textile porosity, the textile porosity under strain, the effective porosity and the effective porosity under strain in TVT produced results that did not meet the most basic requirements that Ethicon was aware of since the late 1990's, early 2000's. As minimal strain was applied to the test sample, the geometric shape of the pores deformed and ultimately collapsed. This deformation led to even smaller pores that make the Prolene mesh highly susceptible to fibrotic bridging, encapsulation by a rigid scar plate and the array of potential complications that occur as a result of this inflammatory process.

Another significant observation during the porosity testing by Prof. Muehl, was the "curling", sometimes referred to as "roping", that occurred in the TVT under minimal strain. We published an article in 2007, [97] in which we showed the tissue reaction and fibrotic ingrowth of PP due to curling/roping of the mesh due to scar shrinkage after H&E staining. [Fig. 6] As strips of mesh begin to curl, the fibers become situated too close together enhancing the inflammatory response and leading to fibrotic bridging. Our recent publication regarding Muehl testing of Ethicon's meshes showed similar characteristics.[98]

[97] Klinge U, Binneboesel M, Kuschel S, Scheussler B. Demands and properties of alloplastic implants for the treatment of stress urinary incontinence. Expert Rev. Med. Devices. 2007; 4(3):349-359

[98] Otto, J., Kaldenhoff, E., Kirschner-Hermanns, R., Muhl, T., Klinge, U. Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates. Wiley Online



Tissue reaction and fibrotic ingrowth of polypropylene with roll up by scar shrinkage. Hematoxilin and eosin staining

Figure 6[99]

Yet another significant observation during the porosity testing by Prof. Muehl both in the current testing as well as the testing published in 2013 was the "fraying" at the edges of mesh which could be seen upon removal from the package but became markedly worse in the TVT mesh sample at minimal strain, especially in the mechanical cut slings. These frayed edges create an increased inflammatory process, and increases the tendency for curling. As fraying occurs, mesh particles can be released into the tissue, increasing the local load with foreign body surfaces, and creating an even greater inflammatory response in the tissues. (See Sections below on Fraying/Particle Loss/Mechanical Cut Mesh (MCM)/ Laser Cut Mesh (LCM)/Curling and Roping

After being subjected to even minimal strain or tension, the TVT slings, like the arms in the Prolift and Prolift +M in our 2013 publication, not only curled, frayed and demonstrated deformation of the pores, they also failed to return to their original or near-original geometric shape and design. This phenomenon of permanent elongation "is mostly due to a rearranging of the sling's architecture and should not be confused with the traditional mechanics definition of plastic deformation of an elastic material."[100] It is my opinion, to a reasonable degree of medical and scientific certainty, that this permanent elongation of TVT slings leads to permanent pore deformation or collapse and increases the risk of an enhanced inflammatory reaction in the human tissues and thus excessive scarring and the cascade of events related to an enhanced and

[99] Expert Rev. Med. Devices 4(3), (2007)
[100] Moalli P., Papas, N., Menefee S., Albo, M., Meyn, L., Abramowitch, D., *Tensile properties of five commonly used mid-urethral slings relative to TVT.* Int Urogynecol J (2008) 19:665-633

chronic inflammatory response. It was determined in 2009 by Ethicon that Prolene mesh in its TVT products would distort irreversibly at 164 grams of force.[101, 102] This irreversible damage would lead to the series of events that is known with permanent distortion or deformation. The TVT original suprapubic sling also undergoes such permanent elongation.

In fact, Ethicon Biomechancial Engineer, Juergen Trzewik, proposed various ideas to prevent pore collapse in Ethicon's pelvic floor meshes. [Figure 5 and 6]

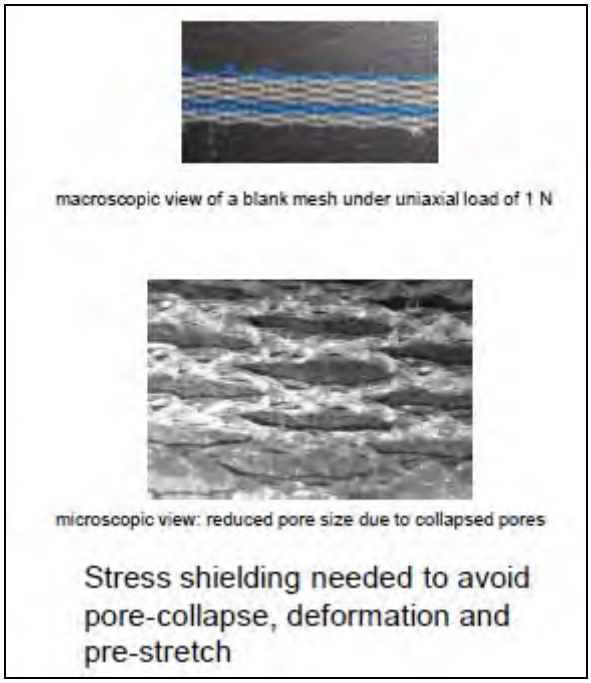


Figure 5[103]

[101] ETH.MESH.00345806 2009 email re Preclin
[102] ETH.MESH.00072085 Final Report PSE Accession Number 05-0396 Project Number 67379
[103] ETH.MESH.02227224 MGPP Thunder Decision Meeting PowerPoint presentation

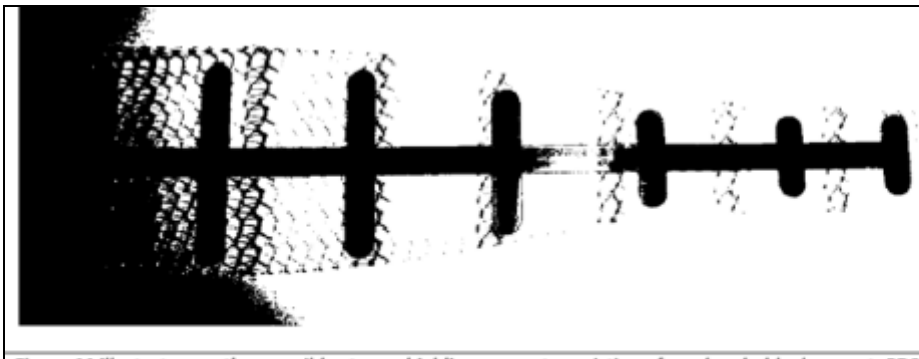


Figure 11 illustrates another possible stress-shielding concept consisting of an absorbable, laser cut, PDS-Film laminated onto the mesh. The PDS Film is bond to the mesh via a heat press process (120 °C, 20 s.). The in-vivo absorbable reinforcing element reduces the pore size kinematics effecting meshes under uniaxial load...

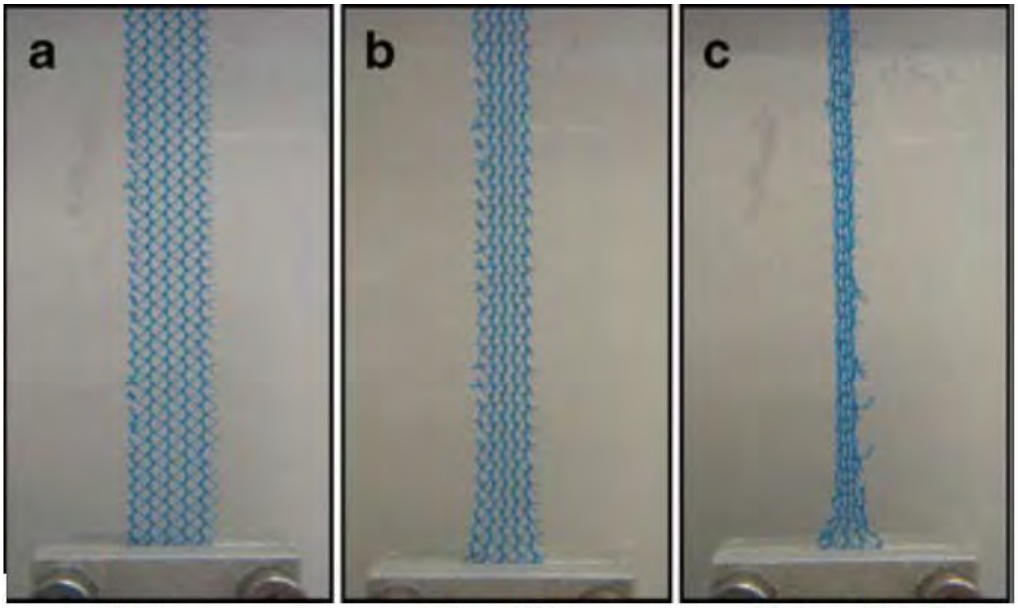
Figure 6[104]

In a 2006 email discussing new French AFNOR standard for testing, a Senior Scientist at Ethicon, Gene Kammerer states, while referencing the Lin article "the article shows the maximum forces applied to the sling under the urethra is about 1N or 100 grams. So, for in vivo function (while the mesh is in the body) a force to elongate should correspond to about 1N"[105], which is in sharp opposition to the tensile forces provided by the Prolene hernia mesh.

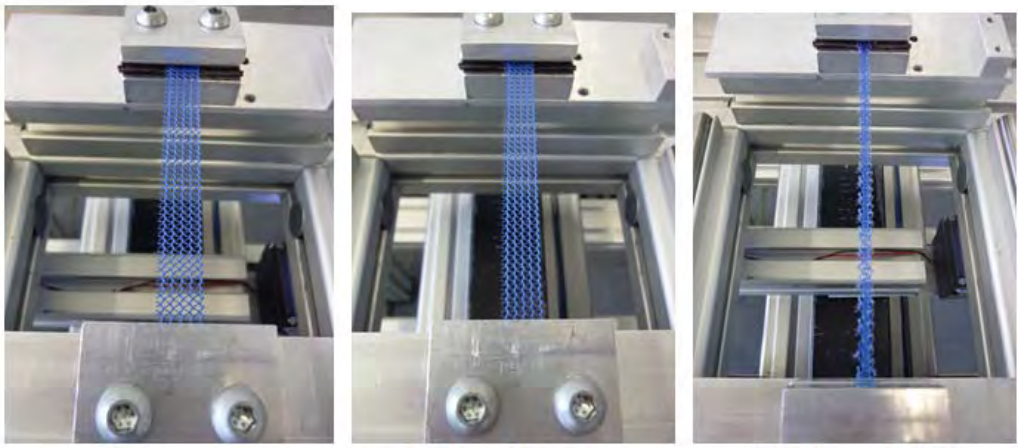
In its "Gynecare TVT Tension-free Support for Incontinence Sales Force Update" dated July 3, 2001, Ethicon states that the properties of its TVT mesh fiber construction was such that the Prolene mesh in TVT "is like a rubber band while other meshes are like silly putty."[106] Based on Muehl's testing of TVT meshes and my work with Prolene mesh both as a surgeon and a researcher, it is my opinion to a reasonable degree of medical and scientific certainty, that this is a clear misrepresentation by Ethicon. A rubber band has elasticity such that when it is stretched, it springs back into its original or near-original shape. Prolene mesh, due to both the polypropylene material and the knitted design, does not return to its original shape upon being subjected to mechanical stresses, which has to be considered as realistic at least during the implantation, but rather, it undergoes permanent elongation and permanent pore geometry deformation as proven by both the Muehl testing and the testing by Moalli et al. as referenced herein.

In testing by Moalli et al. of the Ethicon TVT slings, they found in uniaxial testing, similar to that of Prof Muehl, that "the permanent elongation after C1 (ten cycles between 0.5 and 5 N or roughly 0.1 and 1.1 lbs.) of the Gynecare mesh was different from that of all the other samples tested. Gynecare samples permanently elongated by 17.5 +/- 4.2%, indicating that although very little force applied, there is irreversible deformation of the TVT." The study authors went on to state:

[104] ETH.MESH.02010849
[105] ETH.MESH.00584491 2006 email re AFNOR standards
[106] ETH.MESH.00144301 Tunn R, Picot A, Marschke J, Gauruder-Burmester A, Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol. 2007 Apr;29(4):449-52.



no force | 1 N = 102 g | 10 N = 1.01 kg



no force | 1 N = 102 g | 9,81 N = 1.00 kg

The most important finding of the paper is that Gynecare TVT mesh has a unique tensile behavior which is characterized by an initial region of very low stiffness in which the mesh easily elongates in response to small changes in force…As a result of this behavior, after cyclical loading at low loads…Gynecare mesh permanently elongated by more than 10% of its initial length, **confirming the easy permanent deformability of this mesh that is observed clinically during placement.**" (emphasis added)

In his recent deposition, the Medical Director of Ethicon France, Axel Arnaud, states: "My understanding of this is there are two – normally two types of pores, and when you pull on them, their size might change." He also agrees that when tension is placed on the mesh that the pore sizes change.[107] Both Dr. Arnaud and another Ethicon Medical Director, Piet Hinoul have testified in this litigation that they respect my work and the work of my colleagues, including Dr. Klosterhalfen and that we are highly qualified in this very specific field of biomaterials research on surgical meshes. In fact, Dr. Hinoul testified that he would defer to me as to whether the pores in Ethicon's meshes collapse and deform under load and further stated that if Ethicon's pelvic floor meshes (in that case, Prolift) do collapse and deform making them, in essence, microporous meshes, "Ethicon would not have wanted to sell that mesh." [108,109,110]

My opinion, to a reasonable degree of medical and scientific certainty is that a knitted surgical mesh device like the TVT that is permanently implanted in human tissue must be designed in such a manner that the pores of the mesh do not collapse and deform upon the expected forces of implantation as well as the expected in vivo forces. Under minimal strain, the TVT mesh pores deform and collapse thereby increasing the risk of injury to patients in which it is implanted and is a less safe design than products that better withstand these in vivo conditions and do not display these poor outcomes. Permanent deformation and pore collapse of the TVT mesh leads to fibrotic bridging, scar plate formation, excessive scarring through and around the mesh and a host of tissue complications that can lead to chronic pain, recurrence, erosions, dyspareunia and need for reoperation, to name a few, making it unsafe for its intended purpose of being permanently implanted in a woman's pelvic tissue. As such, Ethicon failed to act as a reasonable manufacturer of surgical mesh intended to treat stress urinary incontinence in women by marketing and selling a product that lacks sufficient stability while undergoing these forces.

E. Mesh Contraction

Mesh contraction, also known as mesh shrinkage, retraction, bunching or wrinkling, is a common phenomenon after mesh implantation that is closely related to scarring and fibrotic bridging. Mesh contraction can be defined by a reduction of the surface area of the original implanted mesh. The surface reduction is due not to shrinkage of the mesh fibers themselves but rather to a retraction of the fibrotic scar tissues around the mesh. Retraction of the scar is a physiologic reaction of maturing scar that is characterized by a constant water loss and, consequently, a subsequent surface area decrease to an average of 60% of the former wound region. It is known to take place in the first few weeks after implantation but can last as long as 12 months or more after surgery. The medical literature and Ethicon's own internal documents

[107] Arnaud deposition 09/17/2013 108:17 to 109:11
[108] Hinoul trial 01/1616 1112:17 to 1114:4
[109] Hinoul deposition 09/19/12 1054:9 to 1055:5; 1063:5 to 1065:11
[110] Arnuad deposition 11/16/12 370:9 to 371:13; 373:20 to 375:2

report that there is considerable mesh contraction of surgical meshes made of polypropylene. [111, 112, 113, 114, 115, 116, 117] [Figures 7, 8, 9a and 9b]

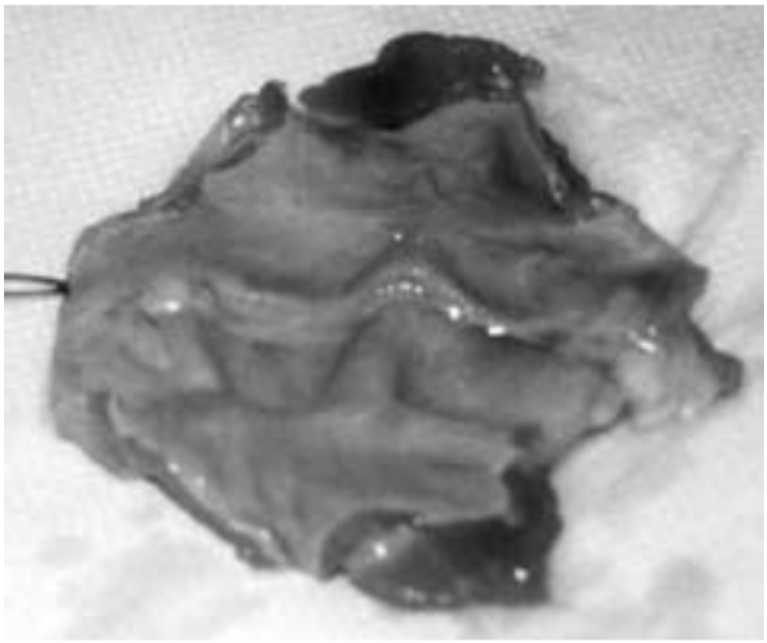


Figure 7[118]

[111] ETH-47802 Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW, Heniford BT Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model..J Surg Res. 2006 Nov;136(1):1-7. Epub 2006 Sep 22.

[112] Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7

[113] Tunn R, Picot A, Marschke J, Gauruder-Burmester A, Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol. 2007 Apr;29(4):449-52.

[114] ETH.MESH.01192895 Velemir L, Amblard J, Fatton B, Savary D, Jacquetin B, Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. Ultrasound Obstet Gynecol (2010)

[115] Letouzey V, Fritel X, Pierre F, Courtieu C, Marès P, de Tayrac R. Informing a patient about surgical treatment for pelvic organ prolapse. Gynecol Obstet Fertil. 2010 Apr;38(4):255-60.

[116] Vollebregt A, Troelstra A, van der Vaart C. Bacterial Colonisation of collagen-coated polypropylene vaginal mesh: Are additional intraoperative sterility procedures useful? Int Urogynecol J. 2009; 20:1345-1351

[117] Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969

[118] Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969

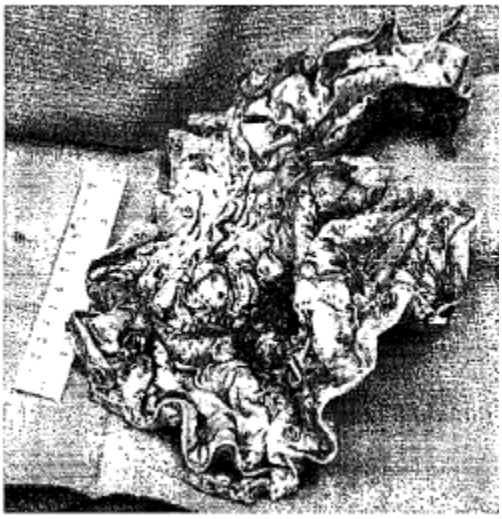


Figure 8[119]

Explanted Prolift Mesh: Int Urogynecol J (2009) 20:523–531

Figure 9a[120]

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[119] Costello CR, Bachman SL, Ramshaw BJ, Grant SA., Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater Res B Appl Biomater. 2010 Aug;94(2):455-62

[120] Blandon R, Gebhart J, Trabuco E, Klingele J, Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J (2009) 20:523-531

Figure 9b[121]

While developing its prolapse meshes, the TVM group in 2006 advised Ethicon of the common occurrence of retraction or shrinkage which then creates a "cord-like" mesh.[122] This issue not only leads to poor coverage leading to recurrence, but will also increase locally the amount of foreign body reaction due to pore collapse. This phenomenon then leads to additional complications depending from the location of the mesh including: pain, dyspareunia, nerve entrapment, increased inflammation, urinary and fecal incontinence, urinary retention, blood vessel injury and others.

In referencing his internal Ethicon paper "Shrinking Meshes?", Ethicon scientist Joerg Holste stated in an email on March 13, 2006 "this was our scientific statement on mesh shrinkage: Basically, small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage during maturing of the collagenous tissue. See my presentation about biocompatibility."[123] That email was in response to a string of internal Ethicon emails in which Ethicon employees were discussing their concerns over a study by Ramshaw in which polypropylene meshes actually shrank more than polyester.[124]

In February of 2007, Dr. Kerstin Spychaj, Ethicon R&D prepared a presentation entitled, "**State of the knowledge in 'mesh shrinkage' – What do we know**?" which she presented at an Ethicon Expert Meeting on February 23, 2007 at Ethicon's Norderstedt facility. Dr. Spychaj did a literature review and concluded that the "ideal mesh" in order to avoid shrinkage would be a

[121] Carolyn Lewis Explant Photos – Dr. Phillipe Zimmern 09/10/13
[122] ETH.MESH.01774758 December 2006 email regarding TVM Group mesh design input
[123] ETH.MESH.05446127 Email from Holste to Engel et al. re: Mesh and tissue contraction in animals
[124] ETH.MESH.05446127 Email from Holste to Engel et al. re: Mesh and tissue contraction in animals

lightweight material (partially absorbable) with a pore size > 1mm and mild but not excessive FBR and wound contraction with swift and adequate tissue growth.[125] Not only had Ethicon determined that shrinkage was obviously critical to the quality of its mesh products, they knew it could cause "vaginal anatomic distortion which may eventually have a negative impact on sexual function." Furthermore, they knew that "its treatment is difficult."[126] Several other Ethicon employees and/or consultants provided testimony or presentations regarding the issue of mesh shrinkage.[127, 128, 129, 130, 131] The Prolene mesh in TVT is both heavyweight and has pore sizes <1mm in all directions, making it highly susceptible to harmful, painful contraction.

Johnson & Johnson hired an outside consulting firm named PA Consulting in 2010 to do a comprehensive and confidential analysis of its surgical meshes in order to look at the increased risk of erosions in its meshes. The final report was issued in June 2011.[132] As part of their investigation and study, PA Consulting interviewed both outside and in-house Ethicon experts. One such expert was Dr. Bernd Klosterhalfen, a KOL for Ethicon and consultant for 20 years. In his interview on January 18, 2011, Dr. Klosterhalfen informed PA Consulting and an Ethicon representative of many variables inherent in Ethicon's meshes that lead to patient complications and failures of the devices.[133] Regarding the shrinkage of Ethicon's meshes, Dr. Klosterhalfen restated what was known or should have been known for greater than a decade:

> At the high level, there are two classes of "shrinkage" observed with mesh implant (Note: the term 'shrinkage' is a misnomer. Tissue reaction over time encapsulates the mesh with connective tissue and effectively `crushes' the mesh into a ball (like crushing a sheet of paper); the mesh does not truly shrink):
>
> - The first is in the immediate short term following implant; the implant is observed to lift and may 'roll up' from its position. This occurs as a result of poor positioning, placement and/or suturing of the implant by the clinician
>
> - The second class of shrinkage is the formation of scar tissue; observed in the longer term (months) following implantation. This scar tissue can reduce and compact, causing the mesh to crumple up.

That last quote is important because as was known widely in mesh science and manufacturing industry, older heavy weight, small pore meshes like the Prolene in Ethicon's TVT slings, experience greater amounts of mesh shrinkage or contraction – up to 50% of the area of the mesh. By this time in 2011, Dr. Klosterhalfen had received approximately 1,000

[125] ETH.MESH.01218361-01218367: Dr. Kerstin Spychaj, State of the knowledge in "mesh shrinkage" – What do we know? 04/05/2007
[126] ETH.MESH.02992139 Lightning Clinical Strategy dtd 11/22/06
[127] Robinson deposition 03/13/12, 260:5-22
[128] Ciarrocca deposition 3/29/12, 340:9 to 340:12
[129] Kirkemo deposition 04/18/12, 105:14 to 108:16
[130] ETH.MESH.03924887 Meshes in Pelvic Floor Repair
[131] ETH.MESH.00870466 06/2/2006 Expert Meeting
[132] ETH.MESH.07192929 6/22/2011 PA Consulting "Investigating Mesh Erosion in Pelvic Floor Repair"
[133] ETH.MESH.07192412 PA Consulting meeting notes with Dr. Klosterhalfen

mesh explant samples over 10 years, and he and I had published a widely-circulated and discussed publication regarding our analysis of these 1,000 explants. He and I had also published a significant amount of peer-reviewed literature regarding explants, animal models and newer designs for more "ideal" meshes and had explained this phenomenon to Ethicon for many years as their consultants. Thus, in this interview, Dr. Klosterhalfen was not informing Ethicon of anything that they did not already know – all of their polypropylene meshes shrink from 30-50%, and the heavier the weight and smaller the pores, the more this shrinkage phenomenon will occur.

It is my opinion, to a reasonable degree of medical and scientific certainty, based upon my background training and experience as a general and abdominal surgeon who used Prolene mesh for hernia repair in dozens of patients and treated Prolene-mesh-related complications in dozens of patients, and based on 20 years of studying Prolene meshes, ten years of which were as a consultant to Ethicon in their preclinical studies of Prolene and other surgical meshes, authoring or co-authoring numerous peer-reviewed publications regarding Prolene mesh, reviewing hundreds of internal Ethicon documents and hundreds of pages of deposition testimony that the mesh used in all of Ethicon's TVT sling products is a heavy weight (105-100 g/m2), small pore (<1mm pore diameter) mesh that leads to an increased risk of intense and chronic FBR, severe and chronic inflammatory response, excessive scar formation, fibrotic bridging, increased risk of mesh encapsulation, scar plate formation, mesh shrinkage, nerve entrapment, chronic pelvic pain, erosions, dyspareunia, recurrence, need for painful and, at times, dangerous revision surgery and multiple, life-long, debilitating injuries in some women.

It is also my opinion, to a reasonable degree of medical and scientific certainty that the Prolene mesh in Ethicon's TVT products contracts or shrinks 30-50% after implantation. This shrinkage was known to Ethicon prior to the launch of TVT in 1998. TVT mesh shrinkage leads to nerve entrapment and thus, chronic pelvic pain, erosions, urinary/defecatory/sexual dysfunction, recurrence and the need for reoperation to remove some or all of the contracted mesh and excessive scar tissue, thereby making TVT unsuitable for its intended use as a permanent pelvic implant to treat stress urinary incontinence in women. As such, Ethicon failed to act as a reasonable manufacturer of surgical mesh intended to treat stress urinary incontinence in women by failing to design a sling device that would resist such a high level of shrinkage.

F. Degradation

Studies as early as the 1960's demonstrated concern over the degradation/oxidation effects of polypropylene when used in the human body.[134, 135, 136] It was presumably due to such concerns that Ethicon adds anti-oxidative additives to its compound batches when formulating and extruding the polypropylene resin – a process that has barely been revisited, retested or changed since the late 1960's.[137]

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[134] Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951

[135] Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246

[136] H.J. Oswald, E. Turi, The Deterioration of Polypropylene By Oxidative Degradation, *Polymer Engineering and Science*, 5 (1965) 152-158.

[137] ETH.MESH.0228619 Prolene Resin Manufacturing Specifications

More recently, there has been growing concern regarding the degradation of polypropylene in prosthetic mesh implants. It is believed that oxidation of the mesh occurs as a result of the chemical structure of polypropylene and the physiological conditions to which it is subjected. This leads to embrittlement of the material, and after implantation in contrast to materials with permanent smooth surface to an increased surface of the prosthesis, due to impaired cellular mobility at the interface to an increased shearing stress, and likely to a stimulation of the inflammatory foreign body reaction, and via subsequent increase of fibrosis eventually enhances the risk for chronic pain.

Costello, et al. reported in 2007 on the degradation of polypropylene surgical mesh. The authors reported that certain by-products of the inflammatory process cause the polypropylene to be more susceptible to the oxidative effects of the metabolites produced by phagocytic cells during the inflammatory response. They saw cracks and other surface degradations such as peeling of the polypropylene fibers under Scanning Electron Microscopy (SEM). [138] [Figure 10] The Costello publication was widely circulated in mesh manufacturing and scientific circles and at conferences, seminars and other lecturing forums that I attended.

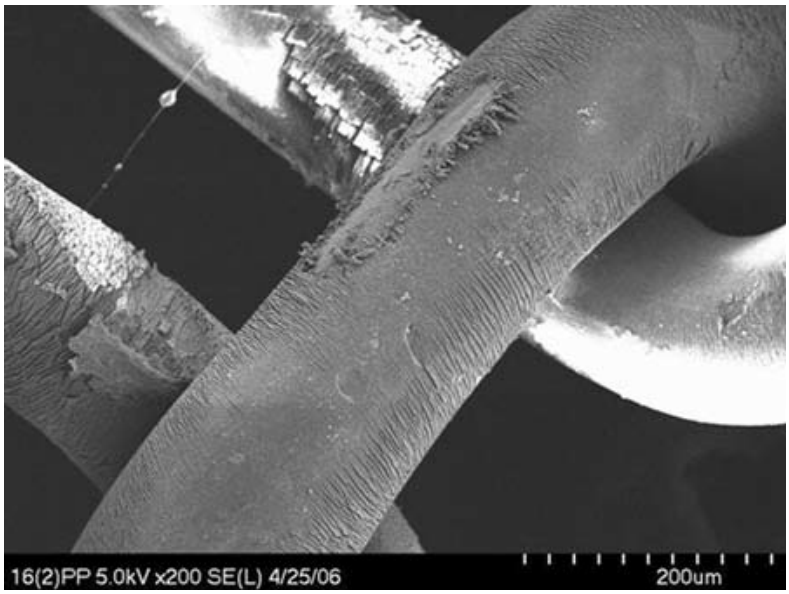


Figure 10

Ethicon was aware of the Costello publication as evidenced by a string of emails in 2007 after the article was published.[139] An Ethicon Medical Affairs employee, Tom Divilio, M.D., referenced the article to fellow employees in both Ethicon U.S. and Ethicon Germany, indicating that one of the authors, a well-known hernia surgeon Dr. Bruce Ramshaw was "challenging our perception of polypropylene as an 'inert' material after implantation." Dr. Divilio of Ethicon stated that "I think it's important that we understand what they are seeing as this group has a well-funded lab that will be looking at explanted mesh in great volume over the next couple of

[138] Costello C, Bachman S, Grant S, Cleveland D, Loy T, Ramshaw B. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient. Surgical Innovation. 2007; 14(3):168-176
[139] ETH.MESH.05588123 7/9/07 Email from Stephen Wolhert to Brigitte Hellhammer re Costello Article

years and our current concepts are going to be challenged. **Would appreciate it if we could think of some study designs that would confirm or refute their assumptions."** (Emphasis added)

Another Ethicon scientist, Dr. Dieter Engel, with whom I worked closely over the years, also commented in that email string "there have been a number of anecdotal reports that polypropylene mesh shows some changes in the surface with time. The Aachen group, who has so far collected more than 1000 explanted meshes, showed examples many years back." This is true.

In that email string, Dr. Divilio also erroneously stated that Ethicon "previously had implanted PROLENE suture into dogs and explants after 10 years revealed no changes in the material." Actually, the Ethicon dog study regarding degradation of various Ethicon sutures was supposed to be 10 years in duration, but was stopped after seven years and did demonstrate degradation of the Prolene material.[140] (See further discussion on Seven-year dog study below.)

Other studies have also demonstrated that polypropylene is not biologically inert. In 2011, Clave, et al. performed a comparative analysis of 100 pelvic mesh explants. The average period of removal was 790.6 days. Over 20% showed such degradation damage to the fibers. [Fig. 11] The article states that the lead author of the study had an educational position for Ethicon Europe.[141] Other authors have also written about the degradative effects of polypropylene in the human body.[142, 143, 144, 145]

[140] ETH.MESH.09557798 7 Year Dog Study
[141] Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. J Biomed Mater Res B Appl Biomater. 2007 Oct;83(1):44-9
[142] Cozad MJ, Grant DA, Bachman SL, Grant DN, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetrafluoroethylene composites: spectral and thermal analysis
[143] Costello CR, Bachman SL, Ramshaw BJ, Grant SA., Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater Res B Appl Biomater. 2010 Aug;94(2):455-62;
[144] Ostergard, D. Degradation, infection and heat effects of polypropylene mesh for pelvic implantation: what was known and when it was known. Int Urogynecol J. 2011; 22:771-774
[145] R. A. Silva, P. A. Silva and M. E. Carvalho, *Materials Science Forum* 539-543 (2007) 573-576.

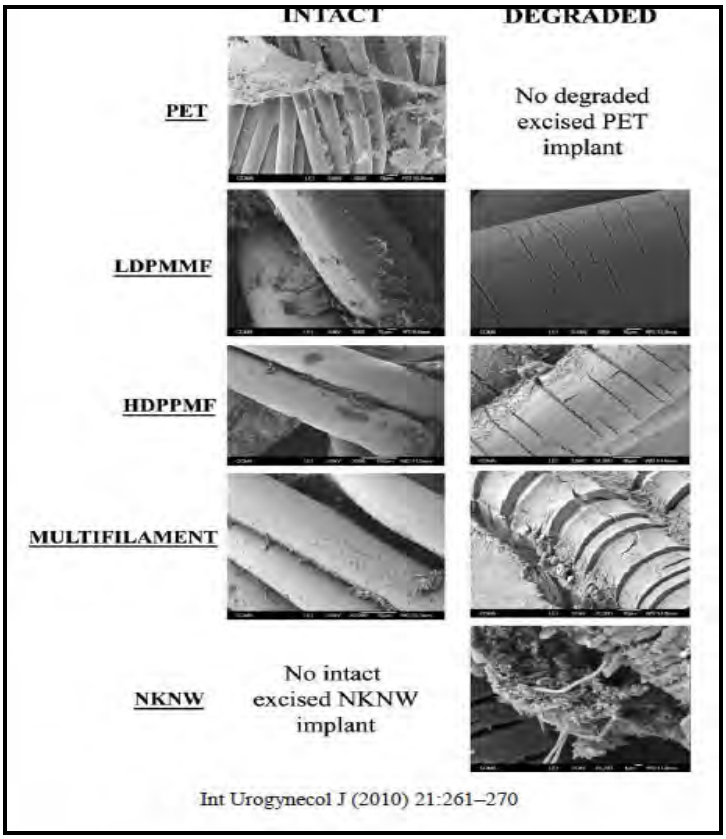


Figure 11

Like the published results of the Costello degradation study, the Clave study has become an important and often-cited article regarding the degradation of polypropylene meshes, and also like the Costello study, Ethicon became aware of the Clave publication and had internal discussions regarding its implications for its surgical meshes; this time, it was the MHRA, the UK equivalence of the FDA, who questioned Ethicon in an email dated 01/26/2012 regarding this latest degradation study.[146] The MHRA request not only asked Ethicon to comment on the degradation of its meshes but also, whether their meshes contract or "shrink".

I observed in many of my studies that macrophages and foreign body giant cells were key-players in 'frustrated phagocytosis'. These cells are known to release mediators such as reactive oxygen intermediates, degradative enzymes and acid, which favor the elimination of cells. However, foreign body giant cells will initiate the degradation of a biomaterial. This high concentration of degradative agents will cause visible damage to the biomaterial that is easily visible in electron microscopy.[147]

Ethicon held meetings to discuss the MHRA email and how to fashion a response. Daniel F. Burkley, MS, "Principal Scientist" in Ethicon's analytical characterization department for 34

[146] ETH.MESH.07226377 03/01/2012 email including 01/26/2012 email from MHRA re Clave Article
[147] Junge, K., Binnebosel, K., von Trotha, T., Rosch, R., Klinge, U., Neumann, UP., Lynen Jansen, P. Mesh biocompatibility: effects of cellular inflammation and tissue remodeling. Langenbeck's Archives of Surgery. (2013) 397;2:255-270

years, was among those who were called to the meetings. Mr. Burkley had been the principal investigator in Ethicon's Seven-year Dog Study.[148]

At his deposition, Mr. Burkley testified that in his 34 years at Ethicon, he was only familiar with this one study that was ever conducted by Ethicon regarding possible degradation of its explanted polypropylene sutures or mesh. Mr. Burkley testified, and his report confirmed, that the Prolene suture showed degradation of the Prolene suture that was still progressing after seven years, whereas the PVDF suture that was studied at the same time showed no such degradation.[149] Ethicon did not fully inform the UK regulatory body about the full results of the dog study nor did they report to the MHRA that they were aware that their meshes contract from 30-50%. The SEM photos from the dog study do indeed show polypropylene degradation, which was confirmed by Mr. Burkley at his deposition:

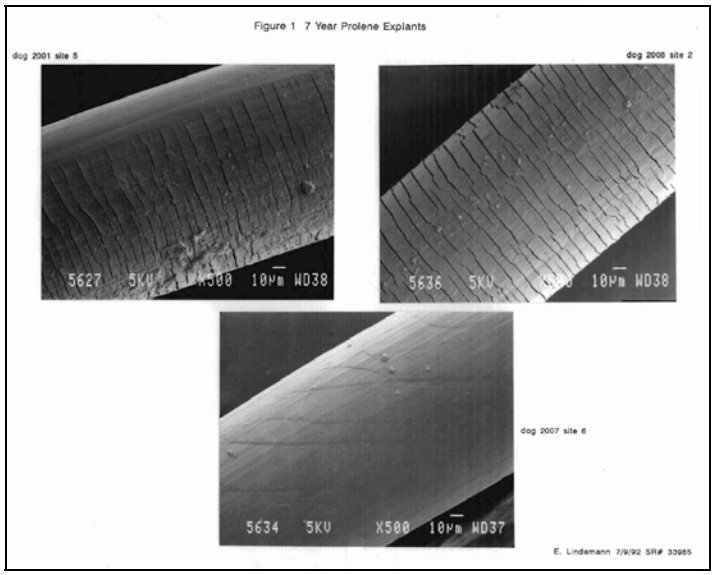


Figure 12

Although the full extent of the clinical implications of a degraded, oxidized surface of polypropylene mesh fibers in human tissue are not completely known, it is my opinion, to a reasonable degree of medical and scientific certainty, that such oxidation and degradation, depending upon the severity, can lead to cracking and peeling of the fiber's surface creating an enhanced inflammatory tissue response due to increased surface area as well as the lack of a smooth surface coming into contact with the tissue. The mesh is not at rest after implantation. As a result of the inherent nature of the physiological forces and stresses being placed on the prosthetic after implantation, the mesh will move and stretch in an anisotropic manner in the tissue. This degrading, peeling surface can damage the tissue in which it is implanted leading to an increased host defense response at the tissue/implant interface and in the surrounding tissue,

[148] Burkley deposition 05/22/2013 & 05/23/2013 pp. 20-24, 139-142, 155-156, 306 -315, 323-327, 368 -371
[149] Burkley deposition 05/23/2013 315:8-13

and it has to be expected that the process will accelerate over time, leading to possible risks in the future that we are currently unable to fully define.

The increased surface area of the cracked and frayed fiber not only causes a more intense foreign body reaction and a greater inflammatory/fibrotic response, but also promotes bacterial attachment, as they are more likely to lodge in the cracked areas of the fiber surface in vivo. This colonization increases the risk of infection that would also create a greater host defense response.

As mentioned above, Ethicon hired an outside consulting firm, PA Consulting Group, to analyze its surgical mesh for the pelvic floor. In an extensive report, dated June 22, 2011, PA Consulting gave Ethicon its opinion that "Polypropylene can suffer from degradation following implant….a process which initiates after a few days post implantation in animal studies."

Numerous reasons are listed as possible causes of such degradation. In fact, one of the clinicians that PA Consulting interviewed when collecting data for the report "proposed that variability in the raw materials, and/or processing thereof, could be affecting the clinical performance and outcomes. He articulated his intention to investigate this hypothesis." A collection of "high resolution images of excised meshes clearly show physical degradation of polypropylene filaments." The report states that these images were collected from Prof. Klosterhalfen, but rather than include them in the report, PA Consulting says that the images are "on file".[150, 151]

Degradation of polypropylene in the human body has been the subject of scientific journals for decades, including one of which was authored by an Ethicon consultant, and at least one internal study; yet Ethicon claims to the FDA, surgeons and patients that the polypropylene material in its surgical meshes is not "subject to degradation or weakening by the action of tissue enzymes." Internal documents reveal that there was knowledge of not only the degradative effects of polypropylene in surgical mesh but also that Ethicon's PVDF mesh, Pronova, was more elastic and demonstrated less degradation than polypropylene.[152]

Despite that fact that there was evidence in the literature since the 1970's that polypropylene degrades in the human body; despite the fact that Dr. Divillio had suggested that it was "important that we understand" the Costello findings and suggested that Ethicon do studies "that would either confirm or refute" the Costello/Ramshaw group's findings; despite the fact that Clave reported that he and his colleagues found degradation in Ethicon's surgical meshes; despite the fact that Ethicon had done its own degradation study that, even though only a suture in the heart of healthy dogs in a clean surgical field, resulted in "progressing" degradation after seven years; despite the fact Ethicon's chief outside surgical pathology consultant for 20 years, Dr. Klosterhalfen had observed degradation in the explants and had informed Ethicon about these findings and provided them images to support his position; and despite the fact that the outside consulting firm that Ethicon had hired to investigate complications with its surgical meshes had informed Ethicon that its meshes "clearly show physical degradation," [153] Ethicon

[150] ETH.MESH.07192929 06/22/2011 PA Consulting report "Investigating Mesh Erosion in Pelvic Floor Repair";
[151] ETH.MESH.09557798 7 Year Dog Study
[152] Klink, CD., Junge, K., Binnebosel, M., Alizai, HP., Otto, J., Neumann, UP,. Klinge, U., *Comparison of long-term biocompatibility of PVDF and PP meshes*. J Invest Surg (2011); 24(6):292-9
[153] ETH.MESH.07192929 6/22/2011 PA Consulting "Investigating Mesh Erosion in Pelvic Floor Repair" Page 35

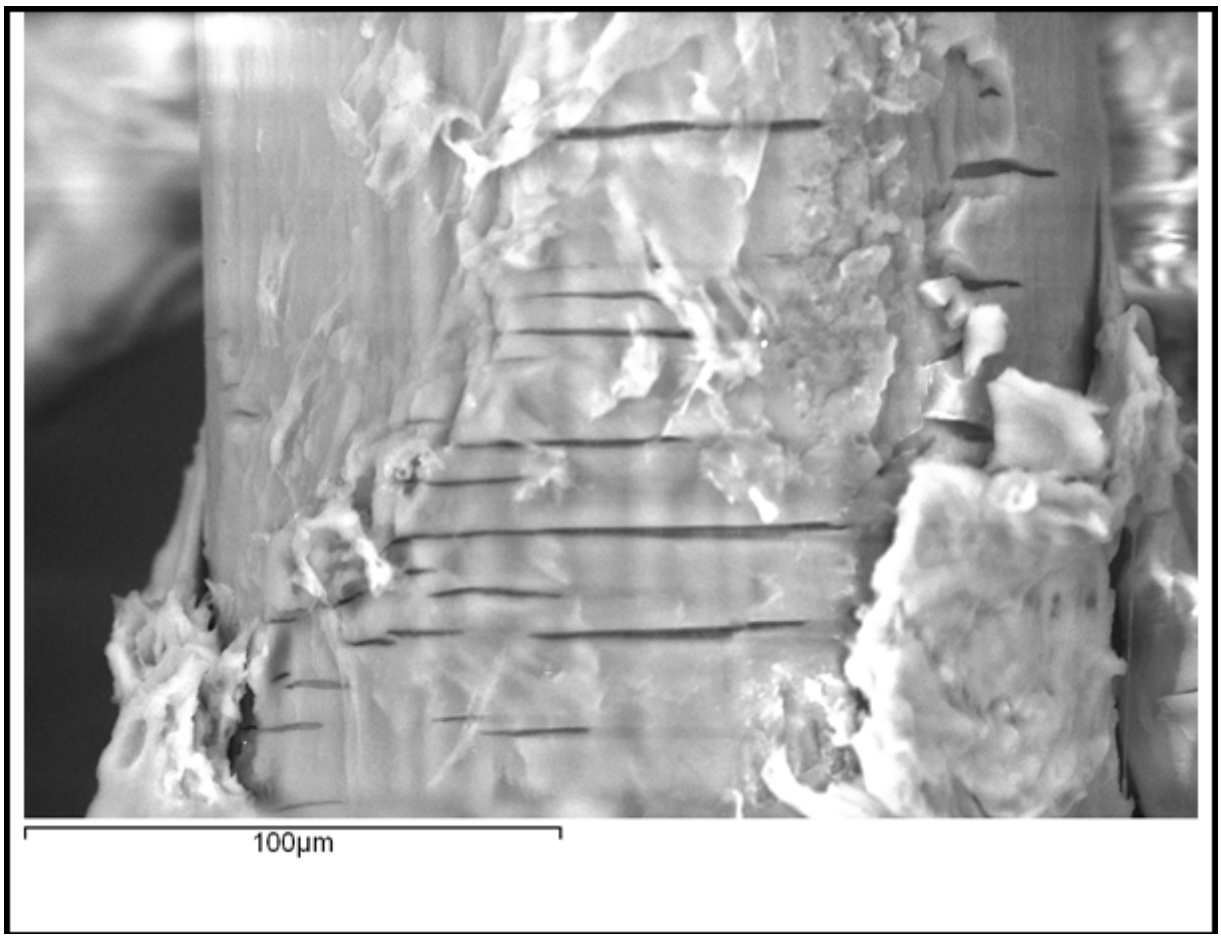
has apparently never performed studies to evaluate its explanted meshes from humans and has only performed one study, 20 years ago, regarding degradation of its sutures in an animal model.

Ethicon claims in its TVT "Instructions for Use" (IFU) to surgeons, that the Prolene mesh material in TVT "is not absorbed, nor is it subject to degradation or weakening by the action of enzymes." [154]

From its own studies, not to mention the abundance of evidence as referenced extensively in this report, in my opinion, to a reasonable degree of medical and scientific certainty, Ethicon knew, or should have known, that claims in its IFU that the Prolene mesh in TVT is not subject to degradation was false and misleading. In fact, Piet Hinoul, Ethicon's Worldwide Medical Director, in a 2009 presentation to other Ethicon employees, stated that "[modern day meshes] are not biologically inert".[155]

I reviewed the report of Dr. Howard Jordi in this litigation regarding his lab's testing of six TVT and TVT-O control samples against 23 TVT and TVT-O explants[156] Dr. Jordi's findings and test results further support my opinions regarding the degradation of Ethicon's TVT meshes in a woman's pelvic tissues. Of the 23 TVT and TVT-O explants that he analyzed, 21 showed cracked, peeling degraded mesh fibers. Furthermore, the Jordi report indicates that testing for the two critical anti-oxidants (Santonox-R and DLTDP) that Ethicon adds to its Prolene mesh fibers used in the Prolene mesh for TVT products is present in the control samples, but virtually non-existent in the explants that they analyzed. It is my opinion, to a reasonable degree of medical and scientific certainty that this leaching of the anti-oxidants out from the polypropylene fibers that is designed to protect the Prolene mesh from oxidation is a design failure of the TVT devices which adds to the cause of surface cracking, fiber pealing and mesh fiber degradation. It is my further opinion, that the TVT mesh will continue to degrade over the life of the product and that the progressive degradation, as seen in the SEM photos by Dr. Jordi, is harmful to women's pelvic tissues by increasing the inflammatory reactions, leading to excessive scarring, fibrotic bridging, scar plate formation, mesh encapsulation, contraction, chronic pain and the host of other scar-related complications set forth in this report. Below are images taken from Dr. Jordi's testing showing degradation, peeling and cracking of the Prolene mesh fiber in the TVT products: [Figs. 13, 14 and 15]

[154] ETH.MESH.02340504 Gynecare TVT IFU 2008-2010
[155] ETH.MESH.01264260 Piet Hinoul 2009 Presentation
[156] Dr. Howard Jordi Report Dated October 12, 2013



40

Figure 13

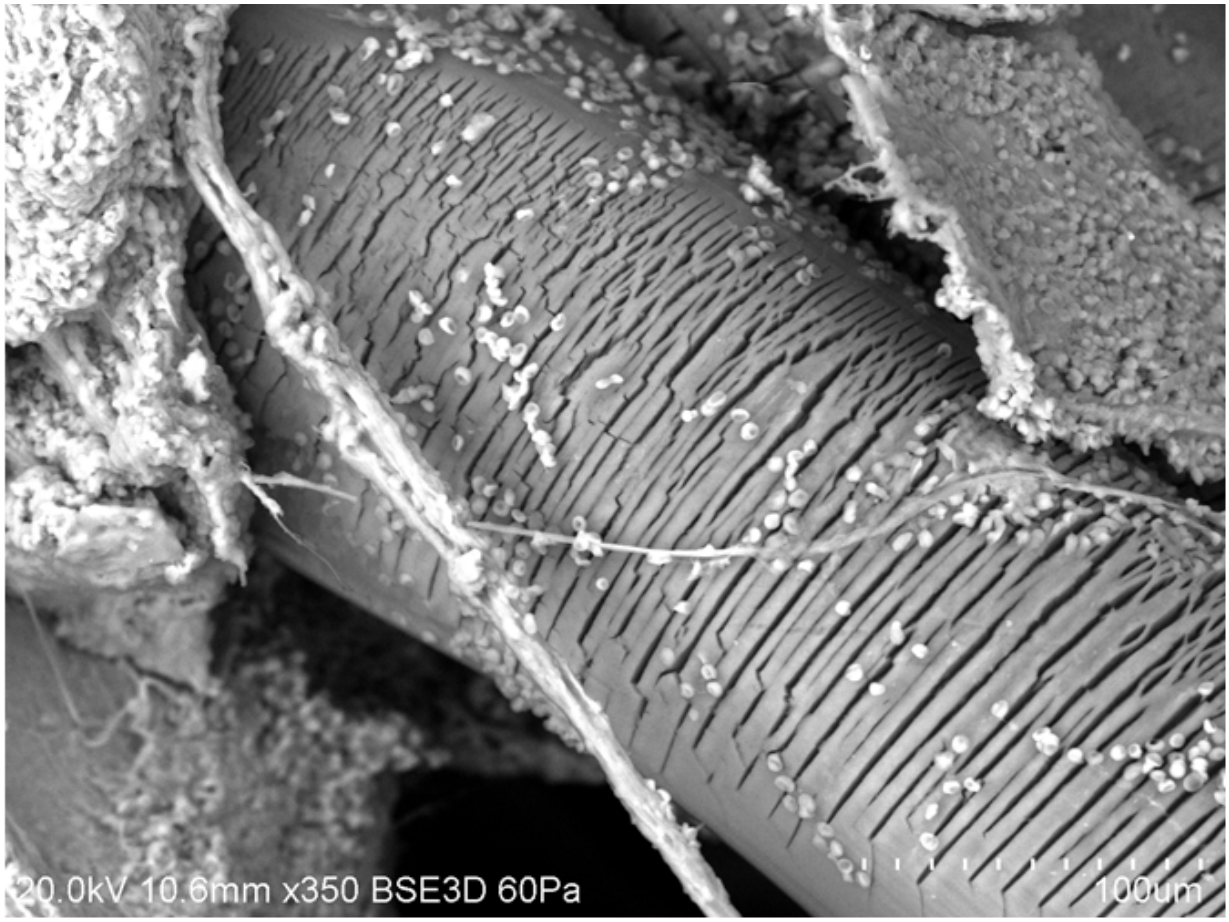


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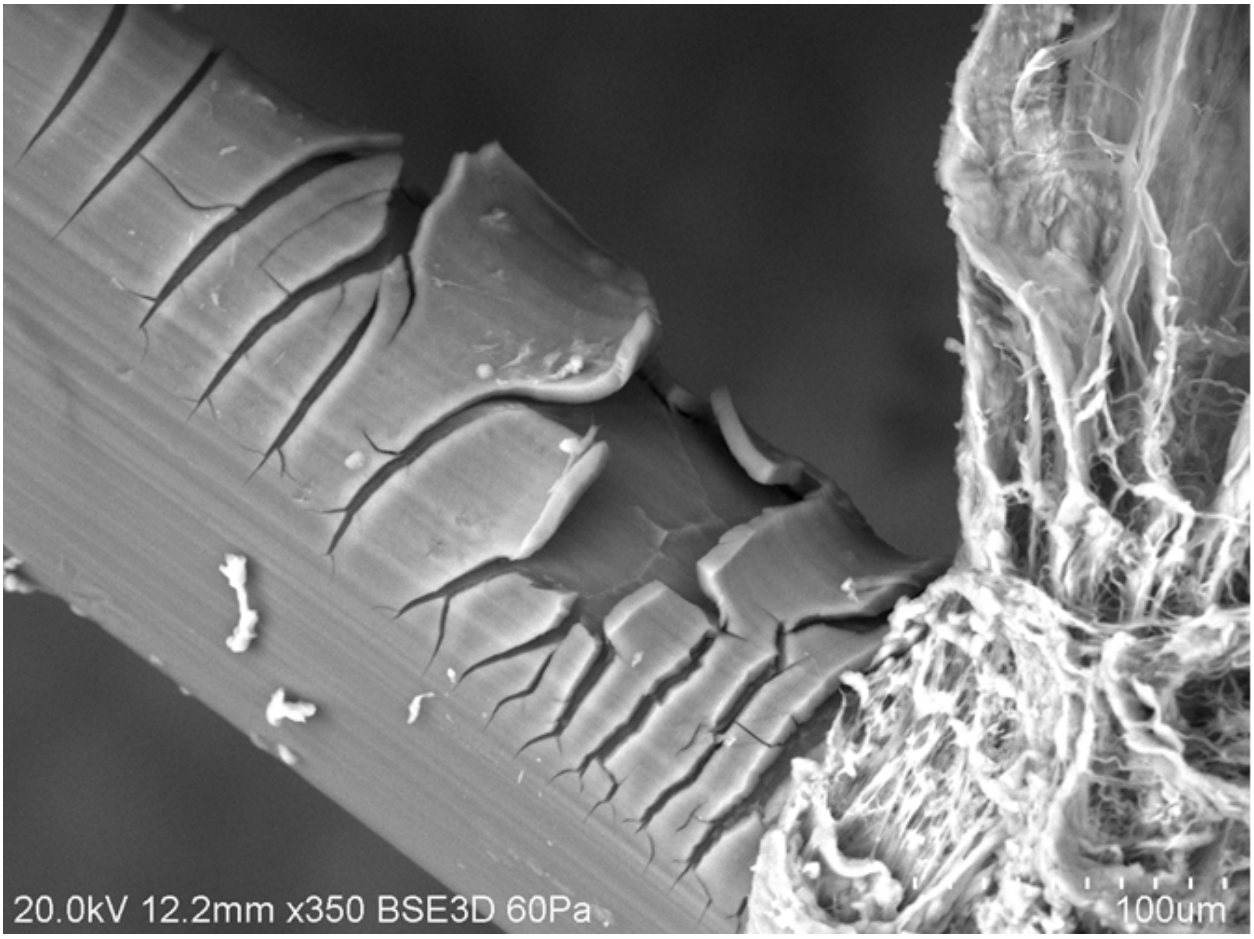
Figure 14



42

Figure 15

In my opinion, it has been proven to a reasonable degree of medical and scientific certainty that the Prolene mesh in Ethicon's TVT products is not biologically inert and does in fact undergo degradation of the mesh fiber after implantation in a woman's pelvic tissues leading to an increased host inflammatory response. When the surface area of the mesh increases, so does the inflammatory response. Also, after the surface of the polypropylene fibers degrades and peels off into the surrounding tissue, the body's inflammatory mediators and chemical products associated with the inflammatory process (like peroxides, superoxide and hypochlorous acid) will continue to attack and degrade the underlying polypropylene. This is especially true given that the only two protective anti-oxidants have leached away from the fibers leaving all of the exposed surfaces of the mesh vulnerable to further oxidation/degradation. Claims by Ethicon in its TVT IFU that Prolene mesh is not "subject to degradation…by the action of tissue enzymes is false and misleading" because the Prolene mesh does degrade in the presence of the chemical process inherent in the body's inflammatory reaction to the mesh in the pelvic tissue of women and thus, the TVT products are not suitable for their intended purpose as a permanent prosthetic implant for the treatment of stress urinary incontinence.

It is further my opinion to a reasonable degree of medical and scientific certainty that these cracked areas provide an area for bacteria to lodge and proliferate, thus increasing the risk of

mesh-related infections. The rough surface also causes increased irritation of surrounding tissue, thus increasing the inflammatory reaction. Therefore, Ethicon had a duty to test the potential degradative effects of the body's reaction to the polypropylene mesh used in its surgical meshes in order to determine whether the anti-oxidants that it has been using for some decades do, in fact, prevent surface cracking and peeling of the mesh fibers in the human tissue and/or whether regardless of the presence or lack of anti-oxidants, their meshes were degrading in the human body. According to their outside consulting group, their other consultants, their own internal studies, abundant literature from almost 50 years, recent studies concerning explanted polypropylene degradation and the testing by Dr. Jordi, it is my opinion, to a reasonable degree of medical and scientific certainty, that Ethicon's TVT mesh degrades in the human body and that this degradative process leads to an increased surface area, increased inflammatory response, increased scarring and the host of patient complications that are associated with a chronic inflammatory reaction in human tissues. Given these opinions and the abundant evidence to support them, the TVT product is not suitable for its intended purpose as a permanent prosthetic implant for the treatment of stress urinary incontinence.

G. Fraying/Particle Loss/MCM/LCM/Curling/Roping

In 2000, surgeons advised Brigitte Hellhammer, an Ethicon employee, that Ethicon's surgical mesh "released particles that migrate through the vaginal wall causing pain during intercourse".[157]

Ethicon considered the hazards and resulting harms in a woman's pelvic tissue due to roping, rough/frayed edges, pore deformation and other possible design failures of the TVT device in its dFMEA for LCM in 2006.[158] Ethicon admits that one of the primary functions of performing a harms/hazards design risk assessment is patient.[159] The Medical Affairs Director for the DFMEA, David Robinson, testified that these were in fact the considerations by the Ethicon team charges with completing the DFMEA.[160] Despite Ethicon's analysis of the risks to women's safety as a result of these known hazards and harms with its TVT product, there were no satisfactory design changes to the Prolene mesh in TVT that adequately address these design failures.

Then, in 2001, Dr. Alex Wang, who was described as "one of the most experienced TVT users in the world", informed Ethicon that he was having problems with frayed mesh and the uneven width of the sling.[161]

In November of 2003, Marty Weisberg, who at the time was the Senior Medical Director of Gynecare, made a note to the TVT file indicating that there had been 58 complaints of mesh fraying since 2000.[162] In that memo to file, he stated "Fraying is inherent in the design and construction of the product. The mesh elongates in places; the mesh narrows in places; and small

[157] ETH.MESH.03924557 Meshes in Pelvic Floor Repair
[158] ETH.MESH.012180109 DFMEA
[159] Smith deposition 06/04/2013 654:1 to 655:20
[160] Robinson deposition 09/11/2013 1070:23 to 1072:25
[161] ETH.MESH.03905472
[162] ETH.MESH.00541379 Memo to File dtd 11/18/03 from Martin Weisberg Re: Mesh Fraying for TVT Devices

particles of Prolene might break off." He also stated that the "stretching of the mesh increases the probability of fraying."

Also in 2003, Pariente published a study in which he evaluated the amount of material shed by different suburethral slings under certain test conditions.[163] Dr. Pariente's conclusion was that "the very high particle shedding for both SPARC (AMS) and TVT (Ethicon) may be of significant long term clinical concern in some quarters." TVT had the highest percentage loss of initial weight at 8.5%. Other authors have commented on the fraying phenomenon of Ethicon's TVT slings as well.[164]

The Pariente article then prompted the French regulatory agency, AFNOR to seek additional information from Ethicon regarding the high amount of particle loss. Ethicon Senior Scientist, Gene Kammerer believed that the method that AFNOR was requesting that they use in order to determine particle loss was unrealistic and too rigorous.[165] Kammerer, who apparently is not a medical doctor, also stated that particle loss "is most likely an aesthetic issue".[166] However, information regarding the impact of particle loss on foreign body reaction and its clinical outcomes is concerning and required further study by Ethicon. These particles cause a greater risk for bacterial adherence[167] and increase the area of inflammatory response surrounding the implant in the tissues. It is, therefore, inaccurate for this Ethicon scientist to simply state that there is no impact on clinical outcome of this loss of particles without clinical testing. Ethicon's Medical Director, Dr. Martin Weisberg, confirmed in his deposition that he was not sure whether or not particle loss and fraying would lead to clinical implications and did not know if Ethicon ever tested particulates for clinical implications.[168] One such implication was a report to Ethicon by a TVT surgeon whose patient had erosion into her vaginal wall following implantation with a TVT sling.[169] The patient's husband reported that during sexual intercourse the "tape appeared frayed and tiny fibers were protruding through the vaginal wall".

In 2004, Ethicon received clinical reports from other surgeons who were using their TVT products of this "crumbling" mesh problem. One of their key opinion leaders ("KOL's") informed the company that "it is embarrassing to see how the tape is crumbling" and it "gets worse if there is a stretch on the tape". This KOL for Ethicon, Dr. Eberhard stated "the quality of the tape is terrible" and "I can't understand that no one will solve the problem for such a long time". [170, 171]

While Ethicon employees such as Gene Kammerer believed this fraying and particle loss to be "an aesthetic issue", actual TVT surgeons, including Ethicon KOL's, obviously believed differently. However, Ethicon chose to continue to sell their TVT mesh as it was with no design

[163] ETH.MESH.01221055 Pariente J-L; An independent biomechanical evaluation of commercially available suburethral slings. Issues in Women's Health
[164] Moalli P, Papas N, Menefee S, Albo M, Meyn L, Abramowitch D; Tensile properties of five commonly used mid-urethral slings relative to TVT. Int Urogynecol J (2008) 19:655-663
[165] ETH.MESH.00583446 5/4/06 email from Gene Kammerer re French Regulatory and Particle Loss
[166] ETH.MESH.0058448 email re Urethral Sling particle loss standards and AFNOR
[167] Jongebloed WL. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261
[168] Weisberg deposition 5/31/13, 469:23 to 470:16
[169] ETH.MESH.02622276 TVT Complaint
[170] ETH.MESH.02180833 Translation of Eberhard Letter
[171] ETH.MESH.02180828 Eberhard complaint

changes to address the problem. Instead, members of the sales and marketing team at Ethicon were instructed to tell doctors that "Prolene is proven to be inert"; that "the particles will not cause any problem"; and that the sales representatives should be "proactive" because "the competition will try to target this!"[172] Ethicon's position during this time was that the particles were not reactive and created no risk to patient safety.[173]

Finally, in 2005, and perhaps in response to the continuing complaints by surgeons and patients, Ethicon attempted to address the problem of the fraying of TVT mechanical cut mesh ("MCM") by instituting a new method of cutting its TVT mesh called laser cutting ("LCM").[174] At first, Ethicon's design engineers evidently felt that testing for critical design considerations like particle loss, flexural rigidity and elongation at various forces was not "critical to quality" and stated this in internal documents as "!!!!!GREAT NEWS FOR TVT LASER CUT MESH!!!!!" and "less work for all of us."[175] Ethicon had evidently determined that although there was greater particle loss with MCM, their test results showed that the difference was not significant enough to be concerned.[176]

However, again the news from the TVT implanting doctors was different than Ethicon's internal conclusions. TVT surgeons were noticing that the LCM was stiffer than the MCM.[177] In fact, at an interview by Ethicon R&D employee, Dan Smith, of one of the founders of the TVT retropubic device, Carl Nilsson, in Helsinki in June of 2008, Dr. Nilsson strongly stated to Mr. Smith that he "Will not use Laser-cut mesh" as it "[d]oes not have the same stretch profile of Mechanical-cut mesh."[178] As Mr. Smith admitted at his deposition, this increased stiffness of the MCM can lead to erosions and pain in patients.[179]

The 2006 Clinical Expert Report for TVT LCM indicated that LCM had decreased particle loss from MCM and that this "decrease would lead to less non-functioning material left in the tissues". [180] There simply is no patient benefit to excess, "non-functioning" polypropylene in a woman's pelvic tissues. More fibers migrating in the tissues create an additional foreign body reaction and inflammatory response at the site of each piece of TVT mesh fiber in the body.

Despite the perceived advantage of decreased fraying and particle loss with its LCM, Ethicon still has the significant problem of a stiffer, more rigid mesh with LCM. In elongation studies conducted by Ethicon in 2004 comparing its MCM and LCM TVT meshes to competitor meshes, Ethicon used an Instron machine (using uniaxial forces) to stretch the meshes to 20%

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[172] ETH.MESH.00865322 email from Charlotte Owens re Reminder on Blue Mesh!
[173] ETH.MESH.03535750 Letter to Herve Fournier re TVT Device, Blue Mesh; ETH.MESH.00541379 Memo re Mesh Fraying to TVT Devices; ETH.MESH.00858252: Memo re Mechanical Cut vs. Laser Cut Mesh Rationale
[174] ETH.MESH.00301741 email from Daniel Lamont re !!!!Great News for TVT Laser Cut Mesh!!!!; ETH.MESH.00394544: Global Regulatory Strategy – GYNECARE TVT – Laser Cutting Project memo; Weisberg deposition 05/31/2013, 487:13 to 488:7
[175] ETH.MESH.00301741; Weisberg deposition 05/31/2013, 490:15 to 491:17
[176] ETH.MESH.01219984 Completion Report for the Design Verification of TVT Laser Cut Mesh; ETH.MESH.00585842 Email from Gene Kammerer re TVT LCM – Particle loss
[177] Smith deposition 08/21/2013, 669:22 to 670: 3
[178] ETH.MESH.04048515 KOL Interview of Carl G. Nilsson; Smith deposition 08/21/2013, 671:3 to 673:7
[179] Smith deposition 08/21/2013, 673:4 to 673:13
[180] ETH.MESH.00167109 Martin Weisberg Clinical Expert Report: Laser Cut Mesh for TVT

elongation.[181] "At 1" of stretch, the laser-cut TVT mesh was about three times stiffer than the machine-cut TVT mesh…" The conclusion in this study focused not on the potential patient complications relative to this three-fold increase in stiffness of the LCM meshes, rather, Ethicon scientists concluded that "[c]utting the TVT mesh with a laser rather than a machine does not impact the established relationship between TVT and its competitors with regard to tensile behavior at low (20%) elongation."

In 2006, Gene Kammerer performed comparisons of LCM to MCM.[182] He placed samples of LCM and MCM TVT mesh under strain to 50% elongation and found that the MCM samples showed "degradation of the structure of the mesh in certain areas where, because of particle loss, the knit has opened and a portion of the construction has been lost. The area may also be stretched and narrowed resulting in roping due to this occurrence." The LCM sample also showed stretching and narrowing, "but is generally less than the MCM". [Fig. 16]

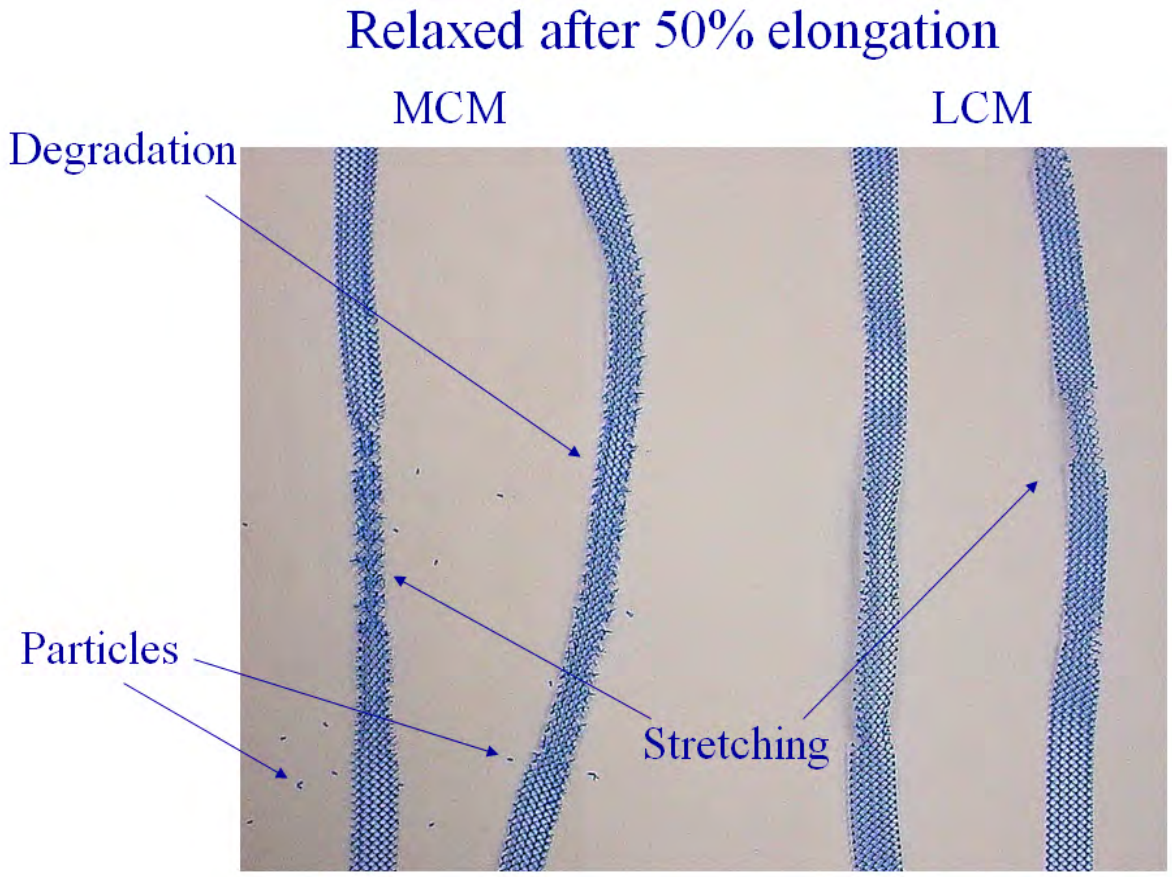

Figure 16

[181] ETH.MESH.01809080 Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)
[182] ETH.MESH.08334244 email from Gene Kammerer re Photographs of LCM vs. MCM

The roping referenced in this Ethicon study, sometimes known as "curling", was seen at low force application in all of the mesh testing of Ethicon's Prolift, Prolift+M, TVT LCM and TVT MCM meshes that I have tested with Prof Muehl. (See **Pore Deformation** Section above re Muehl Testing)

Ethicon Medical Affairs director, David Robinson, admitted at his deposition that the stiffer LCM TVT was intended to address the roping problem. He testified that "customers were expressing they wanted a change with the particle loss, roping, change in tension during sheath removal" and admitted that one of the goals of LCM was to prevent roping and that roping was due to the elasticity problem with MCM TVT.[183]

Based on these results and all of the Ethicon documents referenced above, it is hard to imagine how Ethicon could continue to sell and promote its TVT products without some significant design change to the Prolene mesh in its TVT products. But rather than stopping the sale of the MCM mesh and only selling the LCM mesh that sought to improve upon the fraying and particle loss of its MCM mesh, Ethicon continued to sell BOTH products simultaneously as they did not want to lose a competitive advantage in the market.

In an internal Ethicon email dated May 6, 2005, Ethicon Product Director, Allison London Brown, stated "[t]he basic story here is that the current mesh (MCM) is perceived by some physicians as inferior and we do get a high number of complaints on linting [fraying][184] and roping (mesh particles falling off and the material stretching to the point of being a string). The new material will dramatically reduce the incident of linting [fraying] and should all but eliminate the roping as it stays nice and flat". [185] Ms. Brown asked for her Ethicon colleagues to help her "craft" a story for its TVT customers (surgeons) to "reduce confusion and complexity" and to "tell a nice story without overly admitting that the current procedure may some have perceived aesthetic problems (not clinically relevant problems)."

Other Ethicon employees had similar marketing strategies/concerns in mind. Ethicon U.S. Group Product Director, Kevin Mahar, in an email dated May 24, 2005 had this to say regarding positioning both TVT products in the market at the same time: "Positioning? While we would work with our agency to get this right, my thoughts are we KEEP selling regular TVT (the Colonel's "Original Recipe") to those customers that want/love it…and KEEP going forward with 8 years of data, etc. with the original recipe…we simply ADD these 2 LCM codes and if we have customers demanding LCM, we say, here you go! We do not mislead them that this is the same product, we simply say '…from the makers of TVT…the company 'built' on a tradition of trust, blah, blah, blah')".[186] Earlier in that email string, Ms. Brown stated that the marketing strategists inside Ethicon had "some discussions on the Laser-cut mesh and the impact to base. Most definitely we need to understand how we globally utilize the material and take advantage of the new product, without detriment to the Base business."

[183] Robinson deposition 07/25/2013 492:10 to 493:19
[184] Robinson deposition 07/25/2013 502:21-503:1
[185] ETH.MESH.00526473 Email from Allison London Brown re Laser-Cut mesh
[186] ETH.MESH.00687819 Email from Kevin Mahar re Laser cut mesh

In other internal Ethicon emails, Dan Smith from R&D explains that the TVT and TVT-O meshes cause more urinary retention than its TVT-Secur product because the TVT and TVT-O products "curl and rope which reduces the surface area of the mesh under the urethra and therefore, increases the pressure in a localized point". [187] At the deposition of yet another Ethicon employee, Dan Lamont, he confirmed Mr. Smith's statements saying "[t]here is a potential for roping to occur on the TVT mechanically cut mesh" but "Ethicon chose to continue to sell mechanically cut mesh".[188] The top complaint of TVT surgeons from 2003-2006 was "Mesh Fraying/Roping".[189] (I have viewed an Ethicon TVT implantation DVD which confirms Mr. Lamont's observations that even during the implant procedure, one can see the deformed pores and narrowing of the sling above the scissors and below the urethra while tensioning the sling intra-operatively). [190]

Austrian Ethicon KOL's had also reported problems with fraying and particle loss. An email in 2004 detailed the problem that a preceptor for TVT training in Austria was having when he "noticed that small blue particles kept falling off the mesh, as if the mesh was as he put it 'brittle'".[191] The email states that "[s]ince our mesh is now blue, would it be possible that this was always the case but now it is simply visible as opposed to before the introduction of TVT Blue?" In a later email in that string, Dan Smith stated "I believe the board has to set a directive that can be filtered down to the reps, saying it's OK and it's not an issue, same as TVT clear except you can see it. By the way you can also see it in the package as the pieces fall out of the sheath splits!" He then sates what appears to be a pattern in Ethicon's reaction to reports from surgeons regarding problems with the TVT mesh: "This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate the reps and surgeons UPFRONT that they will see BLUE shit and it is OK."

It is my opinion, to a reasonable degree of medical and scientific certainty that the TVT mesh is a knitted textile design without a sealed border and therefore, it has frayed edges that tend to shed particles of polypropylene before, during and after the surgery. As tension is placed on the mesh, it curls, ropes and sheds these particles, all of which make both TVT Mechanical-cut mesh (MCM) and TVT Laser-cut mesh (LCM) unsafe for their intended purpose of being permanently implanted in a woman's pelvic tissues. The frayed edges and the lost, migrating particles of both TVT MCM and TVT LCM as well as the increased stiffness and rigidity of TVT LCM can all lead to increased inflammatory response, chronic foreign body reaction, erosions, chronic pelvic pain, failure of the implant, dyspareunia, organ damage, urinary dysfunction and the need for surgical intervention. Ethicon failed to act as a reasonable mesh manufacturer by failing to properly design its TVT slings to avoid fraying, particle loss, curling and roping.

It is also my opinion, to a reasonable degree of medical and scientific certainty, that a reasonable mesh manufacturer should be less concerned about how its mesh design compares to

[187] ETH.MESH.01822361 Email from Dan Smith re TVT Secur
[188] Lamont deposition 09/11/2013 25:8 to 25:20; 35:19-36:4
[189] ETH.MESH.00302390 TVT-Base & TVT-O Review for Laser Cut Mesh (LCM) Risk Analysis
[190] ETH.MESH.PM.000004 TVT Retropubic Implantation Video
[191] ETH.MESH.06881079 Email from Dan Smith re Important: 2 TVT Complaints concerning allegedly brittle mesh

its competition, and less concerned about telling a "nice story" to physicians to justify selling "inferior" meshes and more concerned with how its product affects the patients in which it will be permanently implanted. It is my further opinion, again, to a reasonable degree of medical and scientific certainty, that neither the TVT MCM nor the TVT LCM is safe for its intended purpose of being permanently implanted in a woman's pelvic tissues. The frayed edges and the lost, migrating particles as well as the stiffer, more rigid mesh can both lead to increased inflammatory response, chronic foreign body reaction, erosions, chronic pelvic pain, failure of the implant, dyspareunia and the need for surgical intervention.

H. Bacterial Adherence/Biofilms/Mesh-related Infections

Ethicon's Medical Affairs Directors, Axel Arnaud and David Robinson, jointly prepared and presented an internal Ethicon PowerPoint entitled "Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery" by Ethicon's "Academy for the Study of Female Pelvic Floor Disorders" in 2003. [192] In this presentation, some very critical points are raised. According to these surgeons serving as Medical Directors at Ethicon, "It is a challenging task to try to define the ideal material for pelvic floor surgery. Indeed, the scientific knowledge about the use of meshes in surgery is still in its infancy, at least for pelvic floor applications. There are far more products available on the market than randomized comparative trials which could help making a clear distinction among them" and the "absence of strong clinical evidence" made choice of pelvic floor meshes challenging. Despite their admissions that clinical evidence for choice of the proper pelvic floor mesh was lacking, these Ethicon surgeons set out to list the "ideal" characteristics for both incontinence slings and prolapse meshes.

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Drs. Arnaud and Robinson noted the particular challenge in what is considered by many surgeons, including myself, as a sharp turn from 100 years of surgical teaching – placing a foreign body through a "vaginal approach is a rather unique situation in surgery as a prosthetic material is placed through a septic cavity" and "apart from the special condition in the oral cavity and ENT surgery, meshes are never used in such a condition." Perhaps this is why these surgeons listed as the Number One "product requirement" as "1. The mesh must resist infection" with the "rationale" being "High risk of infection since vagina is a septic cavity".

Furthermore, in providing design requirement criteria to resist such infection, Drs. Arnaud and Robinson state that mesh-related infections can be "linked to two factors: 1. The presence of multiple interstices [and] 2. A small pore size". "Interstices" are the "tiny spaces [in between the filaments] which can harbor bacteria."

Dr. Piet Hinoul, another Ethicon Medical Affairs Director, testified at his deposition that: "...Indeed, the chance of introducing a bacteria in that mesh or in that wound is a possibility and, therefore, you have to be extra careful and your meshes must be -- must have a product requirement that even when they get infected, that antibiotics and your immune response can

[192] ETH.MESH.00272548

clear of that infection." [193] As both internal Ethicon documents and abundant scientific literature demonstrate, this is much easier said than done.

Acute and chronic infection lead to poor tissue integration and in many cases, require revision surgery. Post-implantation bacterial colonization is one of the major reasons for the slow and, at times, inadequate integration of surgical implants in the pelvic floor. Thus, the ability of a biomaterial to resist infection has important clinical significance. [194]

One of the major causes of mesh-related infections in patients, who have been implanted with pelvic floor meshes transvaginally, is the formation of what is known as a "biofilm". Ethicon was aware of the formation of biofilms on its transvaginally-placed meshes as noted by the TVM Group, the surgeons who inventors of Ethicon's prolapse repair kit, Prolift. As noted in one of their early publications, "chronic infection is the real problem associated with the placement of such prostheses."[195] In this article, the authors detail the process whereby meshes actually form a protective layer (the biofilm) around the harbored bacteria which actually protects the bacteria from being cleared by the body's host defense response. "The biofilm is an assembly of bacterial colonies fixed upon a support and locked up into an encapsulating matrix. This stable consortium formed is resistant to stress and antimicrobials…The support will be rapidly bathing in a sticky, 'slime-like' magma. Progressively, without any clear signs of inflammation or infection, the prosthesis will loosen."

In addition to Ethicon's knowledge of this critical design concern of its pelvic meshes, there can be found numerous references in the scientific literature to incontinence slings and prolapse meshes becoming infected while passing through the "septic cavity" of what is a "clean/contaminated" surgical field with a transvaginal insertion route.

Vollebregt et al. demonstrated that 83.6% of the pelvic meshes in their study were colonized by different types of bacteria. In that study, 96% of the mesh arms were colonized. An important finding from that study was that repeated disinfection of the surgical area just before handling the mesh did not alter the colonization rate and type of cultured microorganisms. These authors felt that long-term safety data with respect to the risk of infection and erosion in vaginal surgery was still lacking. Furthermore, this study clearly shows that in contrast to the use of meshes in the abdominal wall, contamination has to be considered as a rule when using meshes in the pelvic floor. The potential for increased risks when using alloplastic meshes in a contaminated field should demand further and intense investigations. Although Vollebregt et al. attempted to alter the mesh colonization by repeated disinfection, Culligan et al. found that it is impossible to truly sterilize the vagina before surgery because it is laden with normal inhabitants.[196]

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[193] Hinoul Deposition 04/05/12 111:21 to 112:2

[194] Letouzey V, Fritel X, Pierre F, Courtieu C, Marès P, de Tayrac R. *Informing a patient about surgical treatment for pelvic organ prolapse.* Gynecol Obstet Fertil. 2010 Apr; 38(4):255-60

[195] Debodinance P, et al. *Conceptual advances in the surgical management of genital prolapse – The TVM technique emergence.* J Gynecologie Obstet Biol Reprod 2004 Nov; 33(7); 577-587

[196] Vollebregt A, Troelstra A, van der Vaart C. *Bacterial Colonisation of collagen-coated polypropylene vaginal mesh: Are additional intraoperative sterility procedures useful?* Int Urogynecol J. 2009; 20:1345-1351

Boulanger et al. performed bacteriological analysis of explanted slings and pelvic meshes and published their results in 2007. The most frequent cause for the removal of these meshes was symptomatic vaginal erosion (62%). Bacterial contamination was found in all meshes, two of which were Prolene Soft slings and Gynemesh PFR mesh. Infections were multimicrobial in 31% of the meshes. Progression of infection on the explanted mesh was thought to be explained by the transformation of bacteria in virulent colonies adhering to the fibers. They saw increased rates of infection in multifilamentous mesh due to the increased surface area offered to the bacteria. With pore areas less than 10 µm, bacteria (<1µm) are small enough to colonize while macrophages (16-20 µm) and leukocytes (9-15 µm) are limited to penetrate the interstices of multifilaments. As such, they concluded that large pore, monofilament, PP meshes have superior resistance to bacterial infection. A second mechanism of infection discussed by Boulanger is linked to the adaptive mechanisms of the bacteria itself. The virulence of certain bacteria may be explained by a production of a "slime" or "biofilm" around bacteria colonies. These biofilms will allow the bacteria to remain silent for some period, but over time, they can begin to multiply if an intervening event happens such as alteration of host immune defenses. Chronic infections can thus show up several months or even several years after implantation.[197]

Harrell et al. also studied the bacterial adherence to various mesh prosthetics, noting in their study that bacterial attachment and proliferation on the surface of biomaterials appears to be a key step in acute and delayed mesh infections. Two of the material prosthetic meshes they studied were Vypro and Ultrapro. Vypro had a statistically higher adherence (96%) as compared to the other meshes. The authors felt that this was possibly due to the multifilament nature of Vypro. However, despite the fact that Ultrapro performed better than its predecessor, the authors found > 60% bacterial adherence to this Ethicon product as well. [198]

In what is surely the largest study concerning the risk of mesh-related infections, Choi J. et al. reported on the outcomes of 33,832 explanted hernia meshes in their 2012 article in the *Annals of Surgery*.[199] Their conclusion was that "there is a significant risk associated with [mesh] use in a field with any level of contamination", and they actually discouraged the use of mesh "in ventral hernia repairs in clean-contaminated and contaminated fields".

These "subclinical infections", in other words, infections which are localized to the area around the mesh rather than a systemic infection, have been systematically demonstrated by bacteriological analyses of explanted meshes in other studies as well.[200, 201, 202, 203, 204]

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[197] Boulanger L, Boukerrou M, Rubod C, Collinet P, Fruchard A, Courcol RJ, Cosson M. *Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse.* Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jun;19(6):827-31.

[198] Harrell AG, Novitsky YW, Kercher KW, Foster M, Burns JM, Kuwada TS, Heniford BT *In vitro infectability of prosthetic mesh by methicillin-resistant Staphylococcus aureus.* Hernia. 2006 Apr;10(2):120-4. Epub 2006 Feb 2.

[199] Choi, J et al. Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases.Annals of Surgery (2012) 255:1

[200] Harrell AG, Novitsky YW, Kercher KW, Foster M, Burns JM, Kuwada TS, Heniford BT In vitro infectability of prosthetic mesh by methicillin-resistant Staphylococcus aureus. Hernia. 2006 Apr;10(2):120-4. Epub 2006 Feb 2

[201] Vollebregt A, Troelstra A, van der Vaart C. Bacterial Colonisation of collagen-coated polypropylene vaginal mesh: Are additional intraoperative sterility procedures useful? Int Urogynecol J. 2009; 20:1345-1351

Shah et al., recently published their bacteriological analysis of 50 explanted transvaginal meshes concluding that "colonization of vaginally implanted mesh occurs frequently and bacterial infection may account for pelvic pain in patients with painful mesh and dyspareunia".[205]

Ethicon's outside pathology consultant for many years, Dr. Klosterhalfen, reported the serious nature of secondary, mesh-related infections and their relationship to mesh erosions in annual reports to Ethicon in 2008 and 2009.[206] As he reported, over 80% of the pelvic floor meshes that he analyzed were explanted due to mesh erosions and of those, virtually 100% had associated mesh-related infections.

Johnson & Johnson's outside consulting group, PA Consulting addressed numerous safety concerns regarding the bacterial contamination of meshes in their extensive study of June 22, 2011:

- Inserted transvaginally, mesh traverses the vaginal area that carries many bacteria, hence, without protection, it is virtually impossible to insert mesh devices without contamination;
- Host cells and bacteria compete for dominance over the mesh surface. If the latter prevail the mesh is irreversibly contaminated and the bacteria may remain dormant for long periods, with the possibility of establishing a tissue infection later;
- Mesh surface area may thus be significant in infection rates as it provides a greater potential for bacterial attachment;
- Following insertion, there is a 'race for the surface' of the mesh between host cells and bacteria. If the bacteria colonize the surface, they protect themselves with a biofilm, preventing host defenses from eliminating them
    - The graft area is irreversibly contaminated and the bacteria may remain quiescent for long periods of time, and
    - Surface area is thus important owing to the large area available for potential bacterial attachment
- In the areas where the fibers are linked to each other the filaments form multifilament bundles and the tiny loops and interstices may favor harboring bacteria.[207]

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[202] R. de Tayrac and V. Letouzey, "Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery.," International urogynecology journal, vol. 22, no. 7, pp. 775–80, Jul. 2011
[203] Sternschuss G, Ostergard DR, Patel H., Post-implantation alterations of polypropylene in the human, J Urol, 188 (2012) 27-32.
[204] Laurent Mamy, Vincent Letouzey, Jean-Philippe Lavigne, Xavier Garric, Jean Gondry, Pierre Mares, Renaud de Tayrac, Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection, Int Urogynecol J, 22 (2011) 47-52
[205] Shah, K., Nikolavsky D., Flynn, B. Bacteriological analysis of Explanted Transvaginal Meshes. (2013) AUA meeting
[206] ETH.MESH.00006636 Klosterhalfen Intermediate Explant Reports; ETH.MESH.02157879 Klosterhalfen B., Interim Report Mesh Explants Pelvic Floor Repair
[207] ETH.MESH.07192929 PA Consulting report "Investigating Mesh Erosion in Pelvic Floor Repair"

The design history of Ethicon's prolapse mesh, Prolift, is an example of how Ethicon chose to treat their knowledge of mesh-related infections. In the 2/28/05 DDSA regarding "Mesh Contamination", the Prolift design team did not properly assess the "Probability of Hazard" as to whether the Prolift device was susceptible to mesh contamination. The comment to this risk assessment merely stated "acceptable surgical practices should be followed in the presence of infected or contaminated wounds." [208] In light of the abundant evidence listed above, the suggested mitigation of this hazard would fall short of preventing the risk of a contamination. Failure to properly assess the risk of mesh contamination during the procedure *and* post-implantation was a critical flaw in the design team's risk assessment.

Ethicon claims in its IFUs and Patient Brochures for its TVT slings that the Prolene mesh in the TVT device may only "potentiate an existing infection."[209] In other words, Ethicon did not warn physicians or patients that the TVT slings can cause an infection even where no pre-existing infection exists. Furthermore, in its physician education materials, Ethicon claimed that the TVT does not "predispose to infection."[210] The basis for these claims to surgeons and patients who are relying upon Ethicon to provide them with accurate information as to whether the TVT device would be an appropriate option for them, is a study conducted by an Ethicon Preclinical scientist, Thomas Barbolt.[211] The Barbolt study consisted of the inoculation of a 1 cm x 1 cm piece of mesh with one type of bacteria, Staph A, that he then placed in the back of a rat for four days. Dr. Barbolt's conclusion after this study that lasted for less than a week was that Ethicon's mesh does not "potentiate" an infection. Dr. Barbolt testified at his deposition that this was the one and only study of which he is aware that Ethicon ever conducted in order to claim that its pelvic meshes, inserted through the "septic cavity" of a woman's vagina, is "neutral" to infection.[212] This is hardly solid, reliable scientific data upon which to make the bold assertion to doctors and patients that Ethicon's meshes will not become infected. Equally troubling is that Ethicon only tested Staph A when it knew or should have known that there are many different bacterial species present in and around the vaginal cavity, including but not limited to: Coagulase-negative Staphylococcus, Lactobacillus, Proprionibacteria, Corynebacterium, Group B Streptococcus (S. Agalactiae), Group C, D, G streptococci, Peptostreptococcus, Yeast, Escherichia coli, Klebsiella spp., Bacteroides, Enterococcus, and Proteus mirabilis.[213] Moreover, this claim wholly contradicts Ethicon's employees who have testified that they were aware that the Prolene mesh in TVT could become chronically infected which could lead to more serious complications.[214]

It is my opinion, to a reasonable degree of medical and scientific certainty, that the Prolene mesh in Ethicon's TVT products is susceptible to an increased risk of secondary, mesh-related infections as a result of the bacteria that has both adhered to the mesh during the operative

[208] ETH-03558: 2/28/05 DDSA
[209] ETH.MESH.05225354 TVT IFU ; ETH.MESH.00160615 Patient Brochure
[210] ETH.MESH.00156909
[211] ETH.MESH.03131261
[212] Barbolt deposition 10/10/12 615:19 to 616:11
[213] Vollebregt A, Troelstra A, van der Vaart C. *Bacterial Colonisation of collagen-coated polypropylene vaginal mesh: Are additional intraoperative sterility procedures useful?* Int Urogynecol J. 2009; 20:1345-1351
[214] Holste deposition 7/30/2013 297:24 to 298:14; 307:17 to 308:5; 384:6 to 12; 389:17 to 389:21; 393:5 to 394:7; Arnaud deposition 9/25/2013 754:4 to 785:4; 785:24 to 786:14

procedure and as it is passed through and implanted into a clean/contaminated environment. Ethicon's statements in its TVT IFU that its Prolene mesh used in the TVT products "may potentiate an existing infection" and that the plastic, removable sheath around the sling "is designed to minimize infection" are both inadequate and misleading regarding these secondary, mesh-related infections. Thus, the Prolene mesh in TVT is not suitable for its intended purpose of being implanted permanently in a woman's pelvic tissues, and Ethicon did not act as a reasonable manufacturer by failing to properly study and analyze this critical reality of its Prolene mesh.

VI. BIOMECHANICS

Whether it is for hernia repair in the abdominal wall, stress urinary incontinence or pelvic organ prolapse, the main task of biomaterials used for surgical repair is to strengthen the tissue in which it is implanted and to restore function. The mesh should mimic as closely as possible, and be integrated physiologically into, the tissues, based on a maximum biocompatibility. Such surgical biomaterials should be without serious long-term complications such as recurrence, erosion, infection or chronic pain, and should have optimal handling characteristics for easy, comfortable and safe repairs.

Ethicon's professional education team communicated what it considered to be the "ideal" mesh requirements for pelvic floor repair to physicians that were being trained by Ethicon to use in their surgical meshes. They stated to physicians that the "ideal" vaginal graft should "be histologically well tolerated (inert), resist infection, be easily handled and implanted, incorporate into surrounding tissues, resist mechanical stretch, not shrink, and recreate and maintain the physical characteristics of the supple and distensible vaginal wall."[215, 216]

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Ethicon was aware of the difficulties in defining the biomechanical requirements of the human pelvis. Regarding the biomechanical requirements of the pelvis they admit in their internal documents that although "…the ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed."[217] [Fig. 17]

[215] ETH.MESH.00033325 Professional Education PowerPoint presentation titled "The Science of Augmented Extracorporeal Reconstructive Pelvic Surgery" in which the "Ideal Mesh" is described
[216] ETH.MESH.03906525 Graft or No Graft PowerPoint Presentation
[217] ETH.MESH.02010834 February 16, 2011 report written by Juergen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"

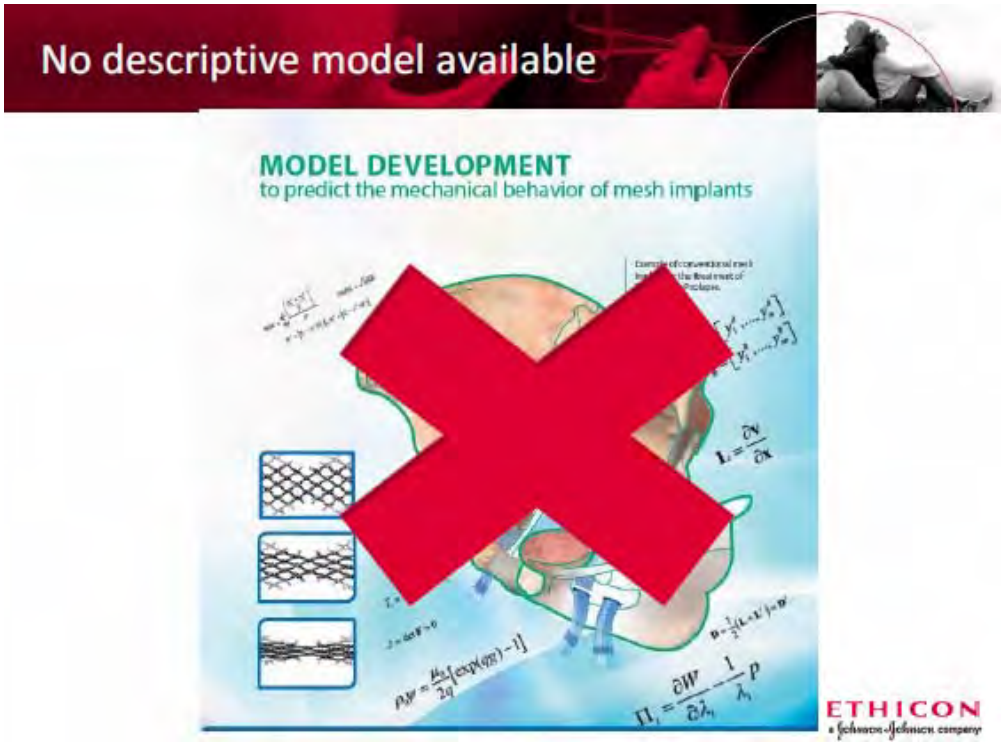

Figure 17[218]

Ethicon recognizes that:

> "…a recent major focus of mesh development and research is the patient's quality of life. Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and 'over-engineered' to exceed the burst strength of the abdominal wall at the cost of losing compliance. Although limited data suggests that, in terms of anatomical and biomechanical outcomes, synthetic polypropylene meshes are superior to biologic meshes, there is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain. In addition, the vaginal tissue to be augmented is often structurally compromised, atrophic, and devascularized. Such poor tissue quality increased the risk of poor tissue incorporation into the mesh potentially resulting in suboptimal healing and mesh exposure or erosion into an adjacent viscous. Moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina compliance. Research has demonstrated that bioprosthetic mesh implantation results in a scarring reaction and subsequent decreased compliance. An ideal quality of prosthetic mesh would be to mimic the compliance of the supported tissue thereby resulting in more comfort and function after implantation. To be able to define the most appropriate design

[218] ETH.MESH.03753245 "Biomechanics" PowerPoint

> parameters for the next generation of pelvic floor prosthesis it is important to generate an advanced understanding of the pelvic floor biomechanics and associated mechanical boundary conditions."[219]

Ethicon scientists recognized that the unique requirements in pelvic reconstructive surgery include the fact that 1) anatomically, the pelvis has a complex, 3-dimensional architecture and vector forces, and 2) functionally, the prosthetic must remain pliable as a result of pelvic organ filling/emptying, tissue pliability, and sexual function.[220] These and other Ethicon scientists also admitted that there is no descriptive model available to predict the mechanical behavior of pelvic mesh implants. Furthermore, Ethicon's Medical Affairs Director, Axel Arnaud, testified that Ethicon's claim that their pelvic floor meshes remain soft, supple and/or pliable was "an illusion".[221]

Other employees at Ethicon, namely, those involved in regulatory and sales and marketing, told a different story. In multiple internal documents, as well as in communications with the FDA, regarding both its TVT meshes and its pelvic organ prolapse meshes, Ethicon claims that "the elastic properties of the mesh adapt to the various stresses encountered in the body." Ethicon admitted to the FDA in 2007 that they had no data to support this statement.[222]

Dr. David Robinson, Medical Affairs Director at Ethicon, gave a PowerPoint presentation titled "Review of Surgical Techniques Using Mesh".[223] The presentation states: "material science has been slow to meet the special requirements of the vaginal environment" and "The vagina is **NOT** the abdomen and it is not similar to any other surgical environment." When this portion of his presentation was discussed at deposition; Dr. Robinson agreed that these are accurate statements.[224]

Another Ethicon PowerPoint may have summed up best the harm to patients of what can occur when a mesh manufacturer, like Ethicon, designs surgical meshes without knowing the biomechanical or physiological environment in which it will be placed. [Fig. 18]

[219] ETH.MESH.02010834 February 16, 2011 report written by Juergen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"
[220] ETH.MESH.00033325 Professional Education PowerPoint presentation titled "The Science of Augmented Extracorporeal Reconstructive Pelvic Surgery" in which the "Ideal Mesh" is described
[221] Arnaud Deposition 11/15/2012 68:10 to 69:13
[222] ETH-65881 Gynecare Prolift IFU
[223] ETH.MESH.00396836 PowerPoint presentation created by David Robinson titled "Review of Surgical Techniques using Mesh"
[224] Robinson deposition 03/14/12 631:21 to 632:12

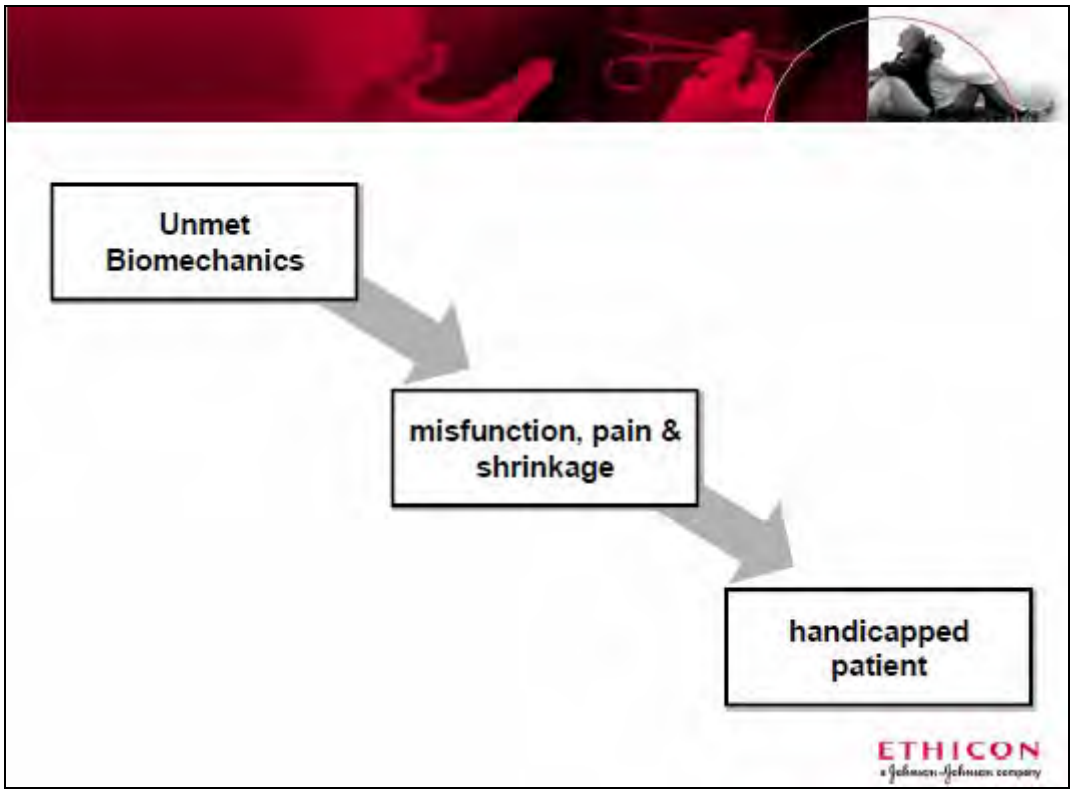

Figure 18[225]

It is my opinion, to a reasonable to degree of medical and scientific certainty that from the time of the launch of TVT in 1998 until the present, Ethicon has continually lacked sufficient knowledge regarding pelvic floor in vivo forces and has never adequately calculated or estimated such forces through appropriate testing and therefore, it has never designed a pelvic mesh that is adapted to the physiological environment in which it is implanted. This mesh design failure by Ethicon in its prosthetic implants for stress urinary incontinence has led to numerous patient complications and causes the TVT sling to be unsuitable for its intended purpose of being permanently implanted in a woman's pelvic tissue. Ethicon failed to act reasonably in designing their slings without designing the biomechanical/physiological requirements of its intended purpose and its intended environment.

A. Physiologic properties of pelvic tissue

The primary difficulty in developing a model to predict the mechanical behavior of pelvic mesh implants lies in the understudied and poorly understood characteristics of the pelvic floor. Drawing conclusions from studies involving animal tissues in an attempt to correlate those findings to the tissues in the human pelvis has severe limitations. As Ethicon has recognized, "[a]nimal models allow for controlled studies, which are useful in understanding the underlying factors that may contribute to the development and progression of human diseases by systematically examining confounding risk factors. However, the need to translate findings to the

[225] ETH.MESH.03753245 "Biomechanics" PowerPoint Presentation

clinic is very important, and therefore understanding how these animal models relate to humans must be evaluated."[226] In fact, in the 2010 Preclinical Efficacy Assessment for Ethicon Gynecare Gynemesh M, it says, "There is no representative quadraped animal model of human vaginal prolapse." It then goes on to say that the most similar pelvic anatomy would be that of a baboon.[227]

At the conclusion of our work in the development of Vypro hernia mesh with Ethicon, my colleagues and I published an animal study in which we demonstrated that the physiological forces of the abdominal wall could be quantified. By properly defining these physiological forces for the first time, we were able to demonstrate how the animal model related to human in vivo behavior in order to improve the textile structure of hernia meshes, and thus, to improve the symmetrical distribution of the retaining forces in all directions. Compared with the considerable restriction of the abdominal wall mobility by Prolene (polypropylene) and Mersilene (polyester) meshes, there was no increase in the bending stiffness after the implantation of the new mesh in rodents. Histological examination showed a pronounced reduction of the inflammatory reaction in the tissues, and the collagen bundles were orientated merely around the mesh filaments instead of forming a scar plate that completely embedded the mesh. By adapting the design of the new hernia mesh to the physiological forces of the abdominal wall, we were able to reduce the amount of prosthetic material which caused less inflammation and less restriction in the mobility of the abdominal wall while retaining the required tensile strength of 16 N/cm. [228] In a clinical trial we could show that the abdominal wall mobility is less restricted after implantation of this mesh material Vypro® whose mechanical characteristics have been adapted to the physiological requirements in comparison to a small pore heavyweight Marlex®, which has to be considered as over-engineered [229]

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No similar, definitive studies have been conducted by Ethicon for the pelvic floor for either its TVT slings or POP meshes. Pelvic tissue is extremely complex; it has a non-linear stress-strain relationship, large deformation before yield, is viscoelastic, inhomogeneous, anisotropic and, when trying to analyze the tissues upon explant, has changing vaginal tissue properties after removal from the body.[230] There have been a number of scientists and surgeons, Cosson, Rubod, Boukerrou, and Boulanger, just to mention a few, who have attempted through various studies to characterize the biomechanical behavior of human vaginal tissue. However, as is evidenced by their studies and acknowledged by Ethicon, "the reported vaginal tissue properties vary extremely for different investigators and different experimental setups; there is no consistent nomenclature for biomechanical properties established; and, the reported material parameters exhibit a strong deviation even between different patients, examined by the same

[226] ETH.MESH.02010834 February 16, 2011 report by Juergen Trzewik and Christoph Vailhe titled "Biomechanical consideration for Pelvic floor mesh design" Exhibit 519
[227] ETH.MESH.04940233 Preclinical Efficacy Assessment for ETHICON GYNECARE GYNEMESH M
[228] Klinge, et al., Modified Mesh for Hernia Repair that is Adapted to the Physiology of the Abdominal Wall; Eur J Surg 1998; 164: 951-960
[229] Schumpelick V, Klosterhalfen B, Müller M, Klinge U. [Minimized polypropylene mesh for preperitoneal net plasty (PNP) of incisional hernias]. Chirurg. 1999 Apr;70(4):422-30.
[230] ETH.MESH.03753245 PowerPoint presentation titled "Biomechanics (Pelvic Forces)"

investigators...more data is needed from humans to help us characterize the differences between normal and pathological tissues, as well as to help us identify appropriate animal models."[231, 232]

Ethicon R&D engineer, Christoph Vailhe testified that newer manuscripts contain more reliable and definitive data regarding vaginal tissue properties including elasticity. However, a review of those manuscripts indicates that they actually continue to demonstrate ongoing debate and a lack of reliable and sufficient data concerning vaginal tissue properties. [233, 234, 235]

Christoph Vailhe further testified that "As of 2012, no validated animal model exists to evaluate mesh erosion in the pelvic floor or to determine the biomechanical forces of the pelvis". [236]

On the one hand, Ethicon merely converted the work on hernia meshes and repackaged it as pelvic meshes assuming, without justification, that a mesh design for hernia application equaled a mesh design for pelvic floor application, despite the differences in anatomy, in the design of the implant and the functional requirements.

On the other hand, Ethicon disregarded our work regarding the danger of heavyweight, small pore hernia mesh and its impact on tissue reaction when using the hernia mesh Prolene for urogynecological slings, while simultaneously promoting the use of large pore, light-weight meshes in abdominal wall surgery and prolapse repair while providing small pore heavy weight meshes for the pelvic floor. It is my opinion, to a reasonable degree of medical and scientific certainty that there is no rational reason why the TVT needs the stability and the amount of material of the Prolene hernia mesh, which only can be regarded as over-engineered for this purpose. It should be mentioned that in the field of abdominal wall hernia repair the use of large pore lightweight meshes has become a standard recommended by guidelines and meta-analysis, and looking at Ethicon products correspondingly large pore meshes as Ultrapro® widely replaced the "Old Construction Prolene mesh", at least in Europe. [237, 238]

Interestingly, from October through December 2008, prior to Ethicon's launch of its new generation POP mesh, Prolift +M, there were required readings by the sales and marketing force to educate them regarding certain aspects of pelvic floor meshes before detailing the product with surgeons. These were known as "Prolift +M Pre-readings". Jonathan Meek, the Prolift +M

[231] ETH.MESH.02010834 February 16, 2011 report written by Juergen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design
[232] ETH.MESH.03753245 PowerPoint presentation titled "Biomechanics (Pelvic Forces)"
[233] Vailhe deposition 06/20/2013 45:23 to 46:11
[234] ETH.MESH.04005863 Yves Ozog, Theoretical and Experimental Evaluation of Implant Materials used in Pelvic Organ Prolapse Repair (Doctoral thesis in Medical Sciences 2001)
[235] ETH.MESH.07191144 Stephan Janda, Biomechanics of the pelvic floor musculature (Thesis)
[236] Vailhe deposition 06/21/2013 251:11 to 252:15
[237] Simons MP, Aufenacker T, Bay-Nielsen M, Bouillot JL, Campanelli G, Conze J, de Lange D, Fortelny R, Heikkinen T, Kingsnorth A, Kukleta J, Morales-Conde S, Nordin P, Schumpelick V, Smedberg S, Smietanski M, Weber G, Miserez M. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS])-Part III.(2009) Hernia
[238] Sajid MS, Kalra L, Parampalli U, Sains PS, Baig MK. A systematic review and meta-analysis evaluating the effectiveness of lightweight mesh against heavyweight mesh in influencing the incidence of chronic groin pain following laparoscopic inguinal hernia repair. Am J Surg (2013) 205(6):726-36

team member in charge of sales and marketing, included in these readings the work that my colleagues and I had done ten years prior. [239]

This leads me to a number of important observations and opinions to a reasonable degree of medical and scientific: 1) Prior to the launch and continued sale of its TVT products and prolapse repair products, Ethicon had not conducted their own studies on its meshes for pelvic tissues that would have built upon the knowledge they had gained a decade prior in order to determine whether their pelvic floor meshes (slings for incontinence and mesh for pelvic organ prolapse) approximated the physiological forces in the pelvis or whether they are over-engineered; 2) four of the seven suggested articles were studies involving hernia meshes from the late 1990's and only two of the remaining studies involved vaginal tissue; and 3) Mr. Meek admitted in an email dated October 29, 2008 that "…up until recently, I was ignorant to the work carried out by the likes of Cobb, Klosterhalfen and Klinge to name a few as it was assumed that they [were] primarily researching Inguinal Hernia repair and it didn't translate to Pelvic Floor. As it turns out, the vast majority of their work is pre-clinical which mirrors the more recent work done by Cosson, Boulanger, Rubod et al. done for the Pelvis."[240]

Mr. Meek's statement is actually only partly true. Yes, our work was to a large extent "pre-clinical" in order to better understand certain design parameters of hernia meshes, in particular to understand the general rules for mesh related complications. However, unfortunately, our work was not applied by Ethicon in its development of TVT and prolapse meshes in that they failed to define the physiological forces in the pelvis and thus to translate this to design considerations for pelvic meshes. The work by Cosson et al. is preliminary in this regard. As Ethicon's own documents point out, there is no scientific basis for the assumption that the biomechanical characteristics of the hernia mesh Prolene fit to the biomechanical requirements of the pelvis. In contrast there obviously are still many unknowns regarding how best to design pelvic floor meshes in light of the still undefined physiologic requirements of pelvic floor and in particular, vaginal tissues, and the tissues in which its slings and the arms of its prolapse meshes are implanted. As Mr. Meek points out later in his email, these studies from the late 1990's have a few key points. Two of these that he communicates to the sales force are that "Polypropylene is the best of a bad lot re integration and retraction and there is a need to develop grafts that mimic the human tissue mechanical properties… [and] the need for grafts with elastic properties to match [the hyperelastic properties of the vagina]."

Unfortunately, Mr. Meek was not the only Ethicon employee who was misguided in this analysis. In May 2007, while the Prolift +M team was recommending updates to the IFU, they also attempted to use our 1998 rat study to support claims in their IFU for Prolift +M. It was disingenuous, at best, and closer to misleading for Ethicon to use a ten-year-old hernia mesh study from the abdominal wall of rats to validate their claim that Prolift +M would "illicit a minimum to mild inflammatory reaction" and "thus incorporate the mesh into adjacent tissue."[241]

[239] ETH.MESH.02207388 Email from Jonathan Meek to Julie Bird et al. re: Prolift +M Pre-Reading
[240] ETH.MESH.02207388 Email dtd 10/26/08 from Jonathan Meek to Julie Bird et al regarding Prolift + M Pre-Reading
[241] Klinge U, Klosterhalfen B, Muller M, Schumpelick V. Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias; Eur J Surg 1998; 164: 951–960

The TVT IFU uses the same language that all of Ethicon's SUI and POP products use: "This material, when used as a suture, has been reported to be non-reactive…"[242, 243, 244] We know that Ethicon has also used our study from 1998 to claim in multiple Ethicon documents and FDA submissions that "the bi-directional elastic property allows adaptation to various stresses encountered in the body." First of all, the mesh we used in our study was Vypro, which was a multifilament polypropylene mesh designed for the abdominal wall. Additionally, Vypro's polypropylene fibers were intertwined with an absorbable component, polyglactin-910. Finally, the mesh in our study was implanted in abdominal tissue, not pelvic tissue. This is quite different from the use of mesh slings and mesh for prolapse repair. To a reasonable degree of medical and scientific certainty, these claims of "non-reactive" suture material and "bi-directional elasticity" that can somehow "adapt" to unknown forces is also false and misleading.

In another unfortunate example of the internal confusion and disparity of knowledge regarding surgical mesh and specifically, the differences between the tissues of the abdomen versus the pelvis, is seen in an email by a top R&D scientist, Joerg Holste, when he stated in March 2007, "My thinking is that a pelvic floor prolapse is clinically comparable to hernia development, because it is part of the abdominal wall."[245] This is not scientifically or anatomically valid from a biomechanical, histological or general functional requirement standpoint. These tissues in these different areas of the body and the organ functioning around them make these environments quite different, as was stated succinctly in the David Robinson PowerPoint slide – "The vagina is NOT the abdomen nor like any other surgical environment."[246]

The scientific reality weights more in favor of an internal Ethicon paper written in 2011 by Juergen Trzewik regarding the biomechanical considerations for pelvic floor mesh design: "We have shown that currently there is an important need for animal models in pelvic floor research…Of course, we ultimately need to know what is happening in the human female…The development of knowledge to understand the mechanics of pelvic floor disorders is imperative; yet, we are only just beginning to determine the necessary criteria on which to base design for pelvic floor implants."[247] This admission by Ethicon comes 15 years after putting TVT on the market, 11 years after putting Gynemesh PS on the market and 6 years after putting Prolift on the market as a "revolutionary" procedure. From the time of the launch of its first pelvic floor mesh, TVT, in 1998 until the present, is it my opinion of a reasonable degree of medical and scientific certainty that Ethicon continues to lack sufficient knowledge regarding pelvic floor in vivo forces and has never adequately calculated or estimated such forces through appropriate testing.[248, 249] These mesh design failure in its prosthetic implants for stress urinary incontinence and prolapse by Ethicon has led to numerous patient complications.

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[242] ETH.MESH.02340504 TVT IFU
[243] ETH.MESH.02340568 TVT-S IFU
[244] ETH.MESH.02340902 TVT-O IFU
[245] ETH.MESH.00078537 Email dtd 03/07/07 from Joerg Holste regarding Lightning 510(k) requirements, "POP is part of the abdominal wall"
[246] ETH.MESH.00396836 "Review of Surgical Techniques using Mesh" by David Robinson
[247] ETH.MESH.02010834 February 16, 2011 report written by Juergen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"
[248] ETH.MES.01156032 Clinical Expert Report for Gynecare Prolift Pelvic Floor Repair System
[249] Vailhe deposition 06/20/13 45:23 to 46:11

B. Strength

Measurements of the tensile strength of human tissue indicate a maximum strength of about 20 N/cm before rupture. Estimates of maximum physiological abdominal wall tensile forces indicate a maximum of 16 N/cm for smaller defects and 32 N/cm for larger defects. These limitations should be provided in all directions and considered as the minimal limit of the force for subsequent tearing. Although testing of sufficient tensile strength in the pelvic floor has been understudied, one can assume that it would not exceed the tensile forces in the abdomen (16 N/cm). In contrast, as the diameter of the pelvis is considerably smaller than the diameter of the abdominal cavity the forces should be assumed to be significantly less.[250]

Ethicon stated throughout its internal documents that strength is an important property of synthetic meshes. It also states that:

> Although in vivo forces and exerted strains on pelvic floor repairs are difficult to quantify, it is unlikely that they are significantly different than those found in the abdomen. Synthetic meshes have been used for years in the repair of abdominal and inguinal hernias and have proven to be of adequate strength to provide tissue support in that region. In fact, many meshes may be over-engineered with respect to strength and mesh density and weight may be able to be significantly decreased. A mesh that has been proven to be over-engineered for reinforcement of the abdominal wall has to be regarded as being over engineered for the pelvic floor in any case. However, the extent of this decrease and the minimum mesh strength requirement for pelvic floor repair is not known.[251]

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It is not possible to design an appropriate surgical mesh if the surgical environment is not understood. It can be reasonably stated that the strength required is far lower than needed for the abdominal wall.

Holste reported in 2005 in an article "**Are Meshes with Lightweight Construction Strong Enough**?" that surgical mesh must provide sufficient biological strength to meet physiological requirements without being over engineered. He added a graph to his publication showing that the maximum tensile strength on the abdominal wall is 150mmHg. The graph demonstrates that Ethicon's hernia meshes Ultrapro, Prolene Soft and Prolene all have burst strengths that are far above the maximum needed strength in light of the maximum abdominal pressure (Ultrapro = 650 mmHg; Prolene Soft = 700 mmHg; Prolene = 1650 mmHg). Holste correctly notes that over-engineered meshes (i.e., those whose strength is far above the maximum requirements of the tissue in which it is implanted thus leaving excessive amounts of foreign material in the body) lead to stiffness, excessive scar plate formation and abdominal wall restriction, all of which in turn lead to complications of reduced patient comfort and chronic pain. However, in that same article, he states that these meshes "possess adequate strength to repair the abdominal wall." He has missed the point. The question is not whether the meshes have enough or adequate strength, the question for Holste and his employer, Ethicon, should have been (and continues to

[250] Ozog, Y, et al. Shrinkage and biomechanical evaluation of lightweight synthetics in a rabbit model for primary fascial repair. Int Urogynecol J (2011) 22:1099-1108
[251] ETH.MESH.02053630 Gynemesh PS "White Paper"

be even to this day) “Do our meshes have more material and/or more strength than is required to accomplish the task of reinforcing the tissues in which they are implanted?”. His conclusions thus run contrary to a proper analysis of the data that he seeks to present given that Prolene Soft is over four times stronger than the maximum tensile strength of the abdomen, and Prolene is over ten times the required strength. [252, 253] [Fig. 19]

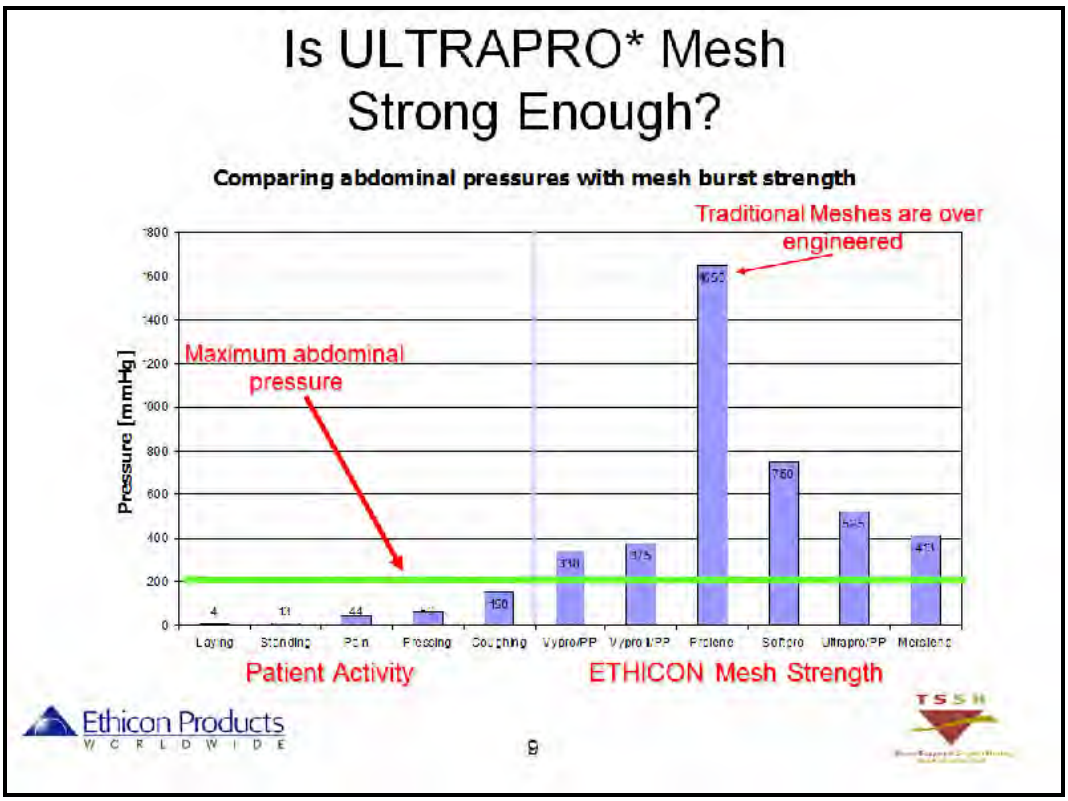

Figure 19 [254]

At his deposition, Dr. Holste agreed that Prolene mesh is ten times greater than the maximum abdominal pressure.[255] Therefore, it can be assumed that TVT mesh is also over-engineered for its intended purpose.

During the development of Project Thunder, it was noted by the design team that as of 2008, pelvic floor material was still over-engineered. “There is no patient-centric PF material!...we need less foreign body material and materials that correlate to measured female pelvic

[252] ETH.MESH.02227224 PowerPoint Presentation dtd 05/09/08 titled MGPP Thunder Decision Meeting
[253] Holste J. Are meshes with lightweight construction strong enough? Int Surg. 2005;90:S10-S12
[254] ETH.MESH.05488362: Ultrapro mesh Pricing Committee Presentation
[255] Holste deposition 07/30/2013 227:17 to 236:16

physiological characteristics"[256] Ethicon's researchers, have admitted that their own "pelvic floor materials are still over-engineered."[257] This would include the mesh in its prolapse mesh, Prolift and certainly includes its TVT slings under the Old Construction, 6 mil heavyweight Prolene mesh.

It is therefore my opinion, to a reasonable degree of medical and scientific certainty, that Ethicon's TVT Prolene mesh is "overengineered" in that it is over 10 times the necessary strength to withstand the in vivo forces while serving to treat stress urinary incontinence and that as a result, that this extremely heavy weight mesh leaves an excessive amount of polypropylene in the pelvic tissues causing increased 1) FBR, 2) inflammatory reaction, 3) risk of fibrotic bridging/scar plate formation/mesh encapsulation, 4) contraction and 5) resulting patient complications.

C. Elasticity

Ethicon knew the importance of a pelvic mesh that was stretchable in all directions due to the complex, dynamic, multi-axial, three dimensional nature of the pelvic region. "Designing a mesh …. First, it is important to consider rigidity / flexibility … [this is] extremely important when considering the dynamic nature of the tissues surrounding the vagina wall. An ideal mesh would be multi-directionally stretchable, easily conforming to tissues in the region of the repair. This would reduce the amount of tension on the fixation sutures allowing the tissue to function normally."[258]

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Ethicon states that its Prolene mesh in TVT, its Prolene Soft Mesh in Prolift, and its Ultrapro mesh in Prolift+M "is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions…The bi-directional elastic property allows adaptation to various stresses encountered in the body." [259, 260, 261, 262]

After Ethicon obtained FDA 510(k) clearance for Prolene Soft, Ethicon used the "bi-directional elasticity" language in its IFU. In 2002, when FDA cleared Gynemesh PS, the same language appeared in its IFU. In July 2007, seven years after Prolene Soft was cleared for marketing, the FDA learned that Ethicon had been selling Prolift kits for two and a half years without proper clearance. In response to Ethicon's subsequent submissions to FDA in an effort to obtain 510(k) clearance to market both Prolift and Prolift +M, the FDA reviewer, Dr. Jiyoung Dang, questioned a number of Ethicon's claims including its claims of bidirectional elasticity and that this property allows adaptation to various stresses encountered in the body.

Various Ethicon employees attempted to find any evidence they had to support these claims. Dr. Christophe Walther (Ethicon Germany) questioned what was meant by "bi-directional elastic

[256] ETH.MESH.02227224 PowerPoint Presentation dtd 05/09/08 titled MGPP Thunder Decision Meeting
[257] ETH.MESH.01405170 PowerPoint Presentation dtd 6/18/07 by Cliff Volpe & Peter Meier entitled "Exploratory Program 'Thunder'"
[258] ETH.MESH.02053630 Gynemesh PS "White Paper"
[259] ETH.MESH.00033325 Professional Education PowerPoint presentation titled "The Science of Augmented Extracorporeal Reconstructive Pelvic Surgery" in which the "Ideal Mesh" is described
[260] ETH.MESH.02340504 TVT IFU
[261] ETH.MESH.02340568 TVT-S IFU
[262] ETH.MESH.02340902 TVT-O IFU

properties" or "allows adaptation to physiological stresses" and asked who was responsible for these statements. Vincenza Zaddem (Ethicon Engineer and Team Leader of Prolift +M) stated "the team felt justified to use the statement 'bi-directional elasticity and that this property allows adaptation to various stresses encountered in the body' because this is the same statement used in the IFUs for PROLENE, PROLENE Soft Mesh and GYNEMESH PS. "Since this is standard data collected for meshes, **without verifying we assumed we had data for UP demonstrating it is elastic in both directions."** (Emphasis added).[263] Apparently, Ethicon also "assumed" they had this data for the Prolift and the TVT before it; however, after searching, Ethicon employees were unable to find data to support their claims and thus, they informed FDA that they would not make this claim in the IFU for the Prolift and had to withdraw it. The claim was also removed from the IFU's for TVT and TVT-O in 2010.

Ethicon had demonstrated its knowledge of the difference and complex elastic properties in the pelvic tissues in different areas of the pelvis. [Fig. 20]

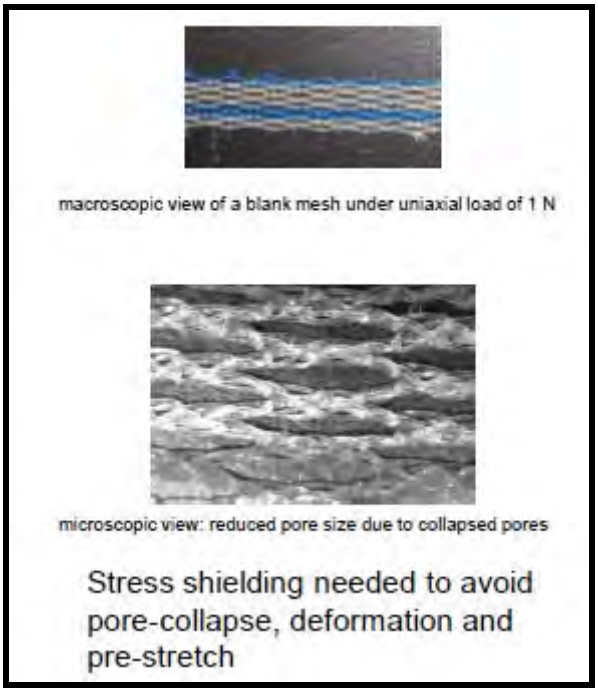

Figure 20[264]

Furthermore, as Ethicon's biomechanical engineer, Juergen Trzewik testified, there are "much more variations within the pelvic floor region that in the human face."[265] He also

[263] .MESH.021989933: Email datd 9/10/07 from Christoph Walther to Vincenza Zaddem regarding "Info needed for FDA – Lightning", in which Zaddem states they "assumed they had data for UP".
[264] ETH.MESH.02227224: MGPP Thunder Decision Meeting PowerPoint
[265] Trzewik deposition 09/18/13 59:25 to 60:3

confirmed at his deposition that despite numerous efforts, there is still no "computer model which simulates the behavior of the pelvic floor tissue."[266]

It is my opinion, to a reasonable degree of medical and scientific certainty, that once implanted, the TVT mesh will be subjected to various three-dimensional and dynamic forces, stains and stresses. Ethicon had no basis for claiming that its Prolene mesh used in TVT had "bi-directional elasticity" given the anisotropic behavior of its Prolene meshes, nor did Ethicon have a basis for claiming that its Prolene mesh, or any of its mesh for pelvic tissue repair, "allows adaptation to various stresses encountered in the body" when Ethicon admittedly has never properly defined what those stresses are in the pelvis much less how the elasticity of TVT properly adapts to those unknown stresses. Ethicon had no basis for claiming "bi-directional elasticity" given the anisotropic behavior of its Prolene meshes, nor did Ethicon have a basis for claiming that its Prolene mesh, or any of its meshes for pelvic tissues, "allows adaptation to various stresses encountered in the body" when Ethicon admittedly has never properly defined what those stresses are in the pelvis.

VII. CLINICAL OUTCOMES/COMPLICATIONS

Poor design leads to poor outcomes. Failure of a mesh manufacturer to properly and thoroughly identify and consider the relationship between the risk of complications and its relationship to design characteristics can have drastic, dangerous and life-changing consequences for patients. Neither surgeons nor patients are charged with the responsibility of designing and testing surgical meshes in a safe manner or being apprised of the latest scientific knowledge regarding the relationship between reported complications and their relationship to potential product design defects; this burden and responsibility falls squarely, and justifiably, on the manufacturer. Likewise, it is the responsibility of the manufacturer, not the physician or the patient, to appropriately warn of the known or knowable safety risks that accompany a particular product.

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When asked about complications related to Ethicon's pelvic meshes, Ethicon former Director of Medical Affairs, Dr. David Robinson testified at his deposition in this matter as follows: "So what we have to do is assure that our product, per se, meets the characteristics that we are describing it having."[267] It is my opinion, to a reasonable degree of medical and scientific certainty, that the inappropriate design of the hernia Prolene mesh for the use in the abdominal wall or in the pelvic floor makes the TVT device a high risk product. Ethicon had an obligation to design a safer product, and to avoid any real or potential risks that may be related to the TVT products.

Thus, it is my further opinion, to a reasonable degree of medical and scientific certainty, that had Ethicon acted safely and reasonably with regard to its design of its pelvic floor mesh products, serious harm and injury to patients could have been avoided.

[266] Trzewik deposition 09/18/13 57:19 to 58:1
[267] Robinson deposition03/13/2012, 131:20-22

Ethicon Medical Affairs Director, Piet Hinoul, testified that Ethicon knew of all of the following complications BEFORE TVT was launched: [268]

- Erosions through vaginal epithelium
- Infection
- Pain
- Urinary Problems
- Erosions that could decrease patient's quality of life
- Dyspareunia
- Need for additional surgeries
- Need for the removal of device
- Urinary Tract Infections
- Dysuria
- DeNovo Urgency
- Mesh Exposure
- Fistual Formation
- Hematoma
- Abscess Formation
- Narrowing of vaginal wall
- Erosion which can occur any time in future
- Contracture of mesh causing pain
- Complications making it impossible to have sexual relations
- Worsening Incontinence

It is my opinion, to a reasonable degree of medical and scientific certainty, that Ethicon's knowledge that there would be women who would experience these complications as a result of the implantation of TVT for stress urinary incontinence imposed on them a duty to act as a reasonable device manufacturer and to either make the appropriate design changes that would lessen or eliminate these serious complications from the usage of its TVT product or to not offer the products in the first instance. It is my further opinion, again to a reasonable degree of medical and scientific certainty, that Ethicon did neither of these things and that this choice to

[268] Hinoul deposition 6/27/13, 542:11 to 582:13

continue selling its TVT mesh with basically the same mesh design from 1974 made the TVT device unsuitable for its intended use as a permanent implant to treat stress urinary incontinence.

Ethicon used Prof. Klosterhalfen as an outside pathology consultant to do histological evaluations at the Duren Institute of Technology of explanted mesh samples received by Ethicon. As of April 2008, he had analyzed 100 such samples. At that time, he prepared an "Interim Report Mesh Explants Pelvic Floor Repair".[269] His findings, summarized, were that "Foreign body tissue reaction followed by secondary fibrosis seems to play a special role in pelvic floor repair. This is important, because soft tissue coverage is thin in pelvic floor repair. Fibrosis and folding in this are inducing mesh erosions and ulcerations".

In June 2009, Prof. Klosterhalfen prepared another interim report regarding his histological examination of another 172 prolapse mesh explants concluding: "In summary, therefore, FBRs and secondary fibrosis seem to play a significant role in prolapse repair…Fibrosis inevitably leads to mechanical irritation, particularly when wrinkling occurs, and should be seen as the basic cause of mesh-induced erosion and ulceration…infection is commonly observed following erosion in the vaginal mucosa."[270]

An internal Ethicon document confirms that "tape exposure/erosion/extrusion [is] very frequently reported", that "[p]atients did not feel there were adequate pre-op consent or risk-benefit assessment", and that patients were concerned with the need for "post-operative dyspareunia" and the diminution of their "quality of life" following TVT and "re-operations-tape excision, removal, re-do sling procedure[s]."[271] Mesh erosions were becoming such a problem with Ethicon meshes that Dr. Peter Meier, a Principal Scientist with Johnson & Johnson Medical in Germany, prepared a 122-page "Clinical Evaluation Report – Mesh Erosions" in September 2010.[272] Dr. Meier reported that, "Mesh related complications may be associated with the mesh material used for reinforcement or the surgical procedure itself. Mesh material related adverse events include infections, erosions, extrusions, mesh shrinkage, vaginal granulation tissue… Additionally, functional problems such as de novo urgency, urge incontinence, dyspareunia and nonspecific pelvic pain may also be observed in certain patient groups." The number one factor that Dr. Meier lists as causing mesh erosions is "pore size and porosity of the mesh" as discussed previously above. Unfortunately, Dr. Meier incorrectly states in this report "…that pore size larger than 75 microns will reduce the incidence of mesh erosions."

As mentioned earlier, on June 22, 2011, Johnson & Johnson received the final PA Consulting Group report investigating mesh erosion. One of the things Johnson & Johnson asked these outside consultants to analyze was Dr. Meier's report from September 2010. In a 50-page report PA Consulting reported that "Of the many variables that influence mesh erosion, pore size is listed first…transvaginal implantation has a higher risk of mesh erosion than trans-abdominal surgery…vaginal area carries many bacteria, so it is virtually impossible to insert mesh devices without contamination…If host cells cannot clear the bacteria on the mesh surface, the mesh is

[269] ETH.MESH.00006636 Klosterhalfen B., Interim Report Mesh Explants Pelvic Floor Repair
[270] ETH.MESH.02157879 Klosterhalfen B., Intermediate Report – Prolapse Mesh Explants 6/2009
[271] ETH.MESH.04081189 Meeting Agenda
[272] ETH.MESH.00869977 Peter Meier "Clinical Evaluation Report – Mesh Erosions"

irreversibly contaminated and the bacteria may remain dormant for long periods with the possibility of establishing a tissue infection later…" [273]

In addition, on December 21, 2011, Chris Vailhe prepared a paper for Ethicon entitled "Polypropylene Mesh for Pelvic Floor Repair (PFR) – Focus on Mesh Exposure – Road to Improvement".[274] Vailhe chose to focus the majority of the paper on "mesh exposure" as it was the highest percentage of adverse events.

I have found in my own work, by examining explanted meshes, that pore size and geometry is the most important factor in the outcome of a tissue repair with a synthetic material. By examining explanted pelvic floor repair meshes my colleagues and I found that erosions, chronic pain and nerve damage were most commonly associated with small pore meshes.

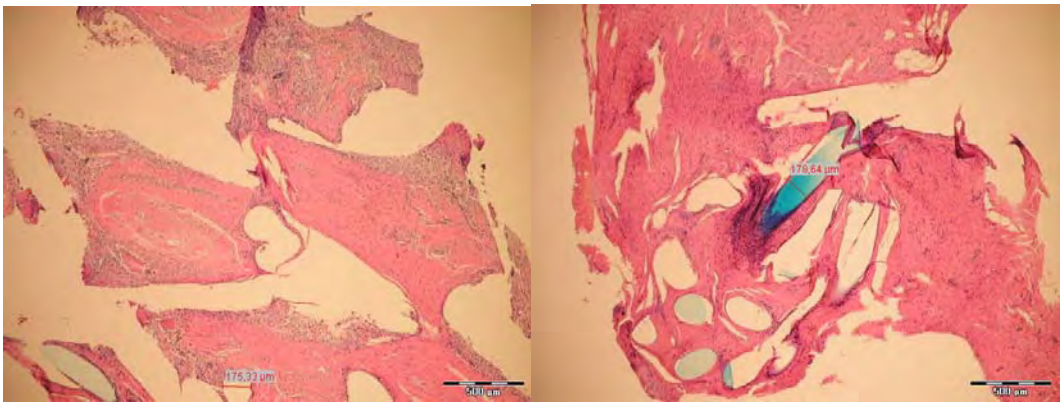
The same holds true in hernia repair. In examining 1,000 explanted hernia meshes, infection and pain as the reason for mesh removal was most often seen in small pore meshes.[275]

In an analysis of 485 explants from the pelvic floor collected at the Institute for Pathology, Düren, we found that a severe fibrosis was seen in > 60% of the TVT-devices (Prolene), about 50% of Prolift (Gynemesh), and 30% of Prolift+M (Ultrapro). Considerable shrinkage was observed in 40% of TVT samples, 20% of Prolift and 10% of Prolift+M. Small pore meshes had significantly higher risk for shrinkage (Risk factor 1.3). Erosion was seen in 20% of the TVT samples, 45% of the Prolift samples, and 60% of the Prolift+M samples. From microscopy, there were seen some "large" pore areas in 30% of TVT specimen, 50% of Prolift, and 90% of Prolfit+M. Noteworthy was that 15% of the explants were extracted from patients with an age of less than 50 years, 40% of patients with an age of less than 60 years, and only 10% of patients with an age of more than 77 years.

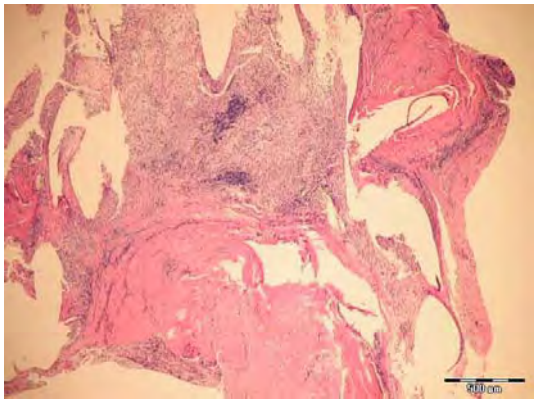
In a recent analysis of 22 explanted TVT and TVT-O specimens, I could confirm in all samples that the mesh structure consists of monofilaments, with a mean fiber size of about 150 µm. All sections showed an intense and chronic foreign body reaction with an inflammatory infiltrate close to the polymer fibers (including macrophages and foreign body giant cells), and dense fibrotic tissue with large deposits of collagen in between, leading to extensive fibrotic bridging. Only in one sole specimen there was visible a single pore filled with fat not being bridged by scar tissue. 19 of 21 specimens showed folding or shrinkage. Using S100 staining as an indicator for nerves, I found in 14 of 21 S100 positive structures in the close neighborhood of the sling (< 1 mm). (Attached as Exhibit "C" are the histopathological images for each explant specimen.)

Below are images from my histopathological analysis of the TVT explants:

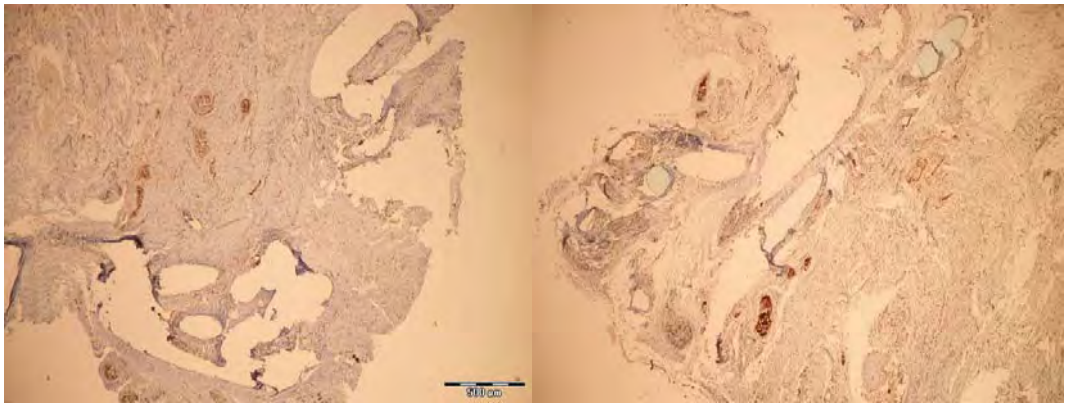
[273] ETH.MESH.07192929 PA Consulting report "Investigating Mesh Erosion in Pelvic Floor Repair"
[274] ETH.MESH.04038032 Chris Vailhe report "Polypropylene Mesh for Pelvic Floor Repair (PFR) – Focus on Mesh Exposure – Road to Improvement
[275] Klinge U, Klosterhalfen B. Modified Classification of surgical meshes for hernia repair based on the analyses of 1000 explanted meshes. Hernia 2012: 1-8

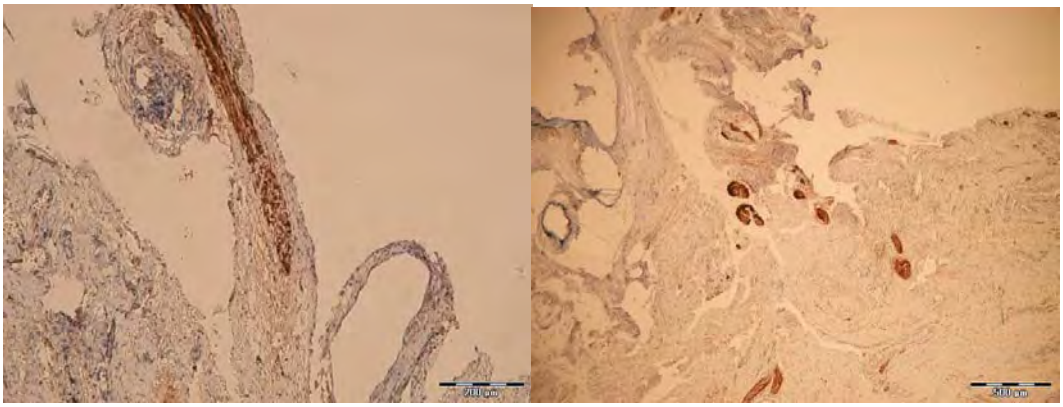


Examples of HE staining, 40x magnification with folded mesh and intense inflammatory reaction at the interface.



Example of HE staining 40x magnification with pronounced acute inflammation

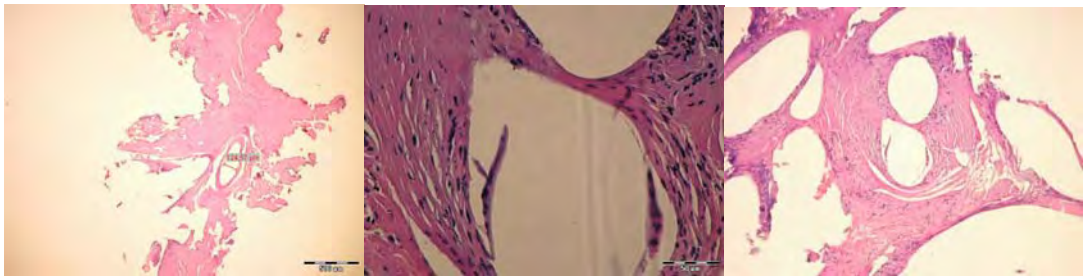




Examples of S100 staining, 40x magnification with nerve structures close to mesh

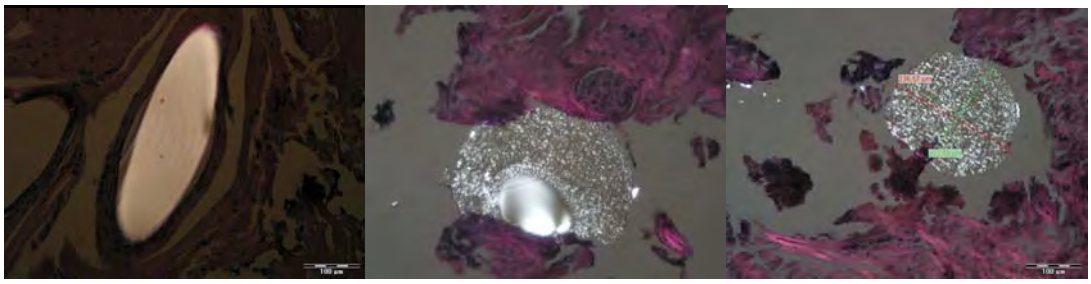
Analysis of a biopsy at the the UT Southwestern Medical Center revealed a) foreign body material, and b) adjacent fibroconnective tissue with foreign body cell reaction.

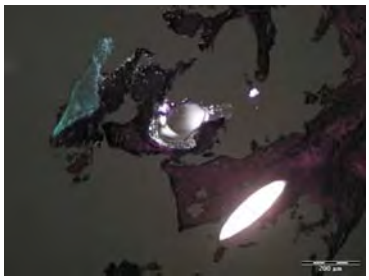
My own microscopic analysis of a biopsy BAL 13-23, confirmed the inflammatory and fibrotic tissue reaction around a textile monofilament device (diameter of the filament 127 µm).



In some areas the polymer of the fibers is found still in place and can be visualized by use of a polarisation filter (Olympus U-pot, Japan). In some areas there are separate polymer particles without any connection to the mesh filaments.

Some areas of the polymer showed considerable inhomogeneity of the crystal structure that can hint to a present change of the crystal structure.





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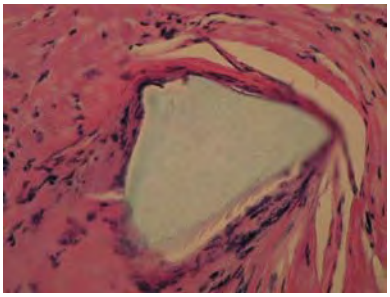
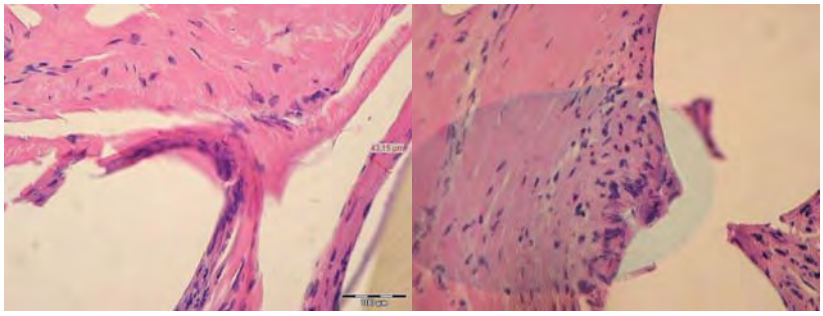
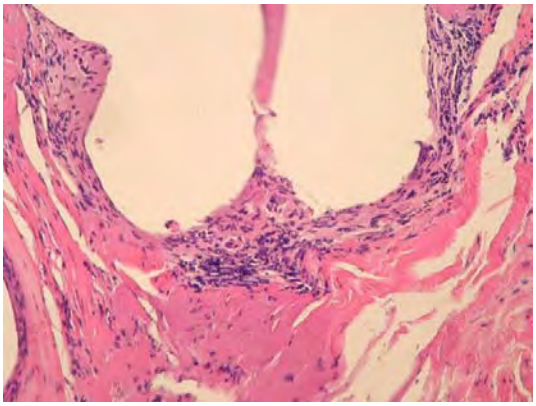
Around the separate particle the usually tissue reaction can be seen as known from the tissue reaction to polymer fibres.



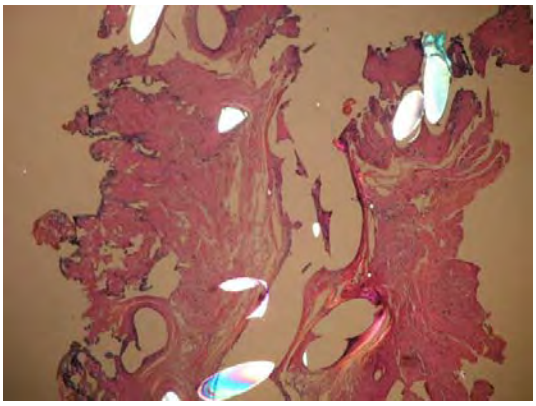
The tissue reaction to the polymer consists of an inner zone of polymorphous mononuclear inflammatory cells with some confluent foreign body giant cells as sign of a chronic inflammation, mainly located at the interface to the polymer.



The thickness of this inflammatory infiltrate is around 50 µm, but in some areas with close distance between the filaments the entire space completely is filled out by this inflammatory infiltrate. In some areas the accumulation of inflammatory cells indicates a more active acute inflammatory reaction.

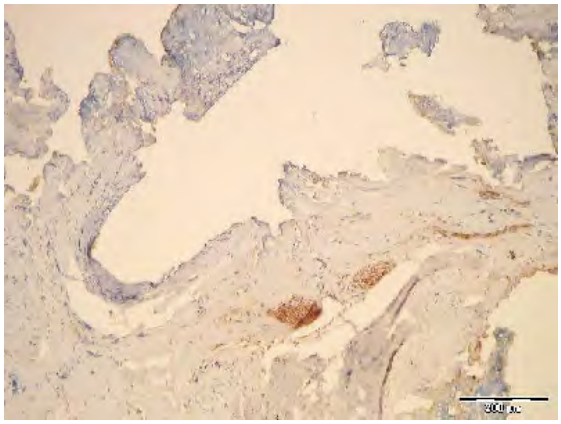


In some sections the mesh shows a folding with doubling of the layers.



The entire space between the fibres with their inflammatory infiltrate is filled out by fibrous scar tissue. In these sections there is no pore that is not filled by this (without “bridging”).

S100 as indicator of nerve cells showed a nerve structure of 100 µm in diameter close (less than 100 µm) to the granuloma around a fibre.



These images are all consistent with the expected adverse tissue reaction that has to be expected in human tissue in response to a heavy weight, small pore mesh.

What we originally found in preclinical studies in animals that small pores lead to extensive bridging fibrosis, could be confirmed in explanted meshes of the abdominal wall, could be confirmed in explanted meshes from the pelvic floor and now can be confirmed in 22 TVT explants. A small distance between the mesh fibers is filled by scar tissue, whereas large pore constructions provide the opportunity for the body to fill the pore with fat tissue. Correspondingly, large pore meshes have been found to be beneficial in preclinical studies and when used in humans in both the abdominal wall and the pelvic floor. Thus, any use of a small pore mesh is proven to be related to an increased fibrotic reaction and thereby with risks to the patient. Accordingly, any mesh construction should provide the largest pores that fit the biomechanical needs and exclude any unnecessary risks.

Clearly, not all women will have all of the complications that many other women will have after implantation with the TVT slings; however with the current Prolene TVT design the risk for fibroconnective complications is higher than with a non-overengineered material reduced large pore designs. The reason for the inter-individual variations have been sparsely studied and is not clearly understood. To my knowledge, after reviewing thousands and thousands of pages of internal Ethicon documents and deposition testimony, Ethicon has performed no appropriate studies in order to determine in which women, serious, life-altering complications may occur due to implantation of TVT slings. A reasonable manufacturer and seller of sling products that will be permanently implanted in women, in my opinion, and to a reasonable degree of medical and scientific certainty, should have studied this vastly understudied reality that many women will face. Ethicon has therefore failed to act as a reasonable manufacturer in this regard.

At Ethicon expert meetings, Dr. Klosterhalfen told Ethicon that "every individual reacts different to mesh."[276] Ethicon's Medical Director, Piet Hinoul testified that "There is, you know, the inflammatory response is individually different."[277] Dr. Hinoul and his colleague, Charlotte Owens, another Ethicon Medical Director, both also testified that prior to launching its pelvic

[276] ETH.MESH.00870466-0476
[277] Hinoul deposition 04/06/2012545:23-546:2

meshes for sale in the U.S., Ethicon knew that some women would have severe, chronic, life-altering inflammatory response to its pelvic meshes.[278] Despite these critical admissions by Ethicon's top Medical Directors, Ethicon has not performed studies to help address this issue and to help surgeons and patients determine if the risk of the TVT procedure outweighs the benefit for them.

Some research has been conducted in this area by myself and others in order to attempt to determine if certain patient co-morbidities might predispose them to inappropriate wound healing, mesh failure, greater inflammatory response and other mesh-related complications.[279, 280, 281, 282]

In a recent publication, Ruiz-Zapata et al. found that fibroblast function, and thereby, wound healing, is compromised in patients with pelvic floor tissue disorders, like pelvic organ prolapse.[283] This article demonstrates that there is a considerable variation among patients that have healthy versus unhealthy pelvic tissues as a result of fibroblast function. We similarly have seen that fibroblasts from patients with a hernia disease behave differently as those of patients without a hernia. [284, 285, 286, 287, 288, 289]

It is therefore my opinion, to a reasonable degree of medical and scientific certainty, based on my surgical practice using and teaching complications with Prolene, my work in helping design better surgical meshes as an Ethicon Consultant, my work in the histopathological analysis of tissue response to surgical meshes and my analysis of 1,000 hernia explants and over 500 pelvic floor explants, that the Prolene mesh in Ethicon's TVT products is not a safe design for patients, is too heavy, has pores that are too small, is "over-engineered" for its intended purpose, and leads to significant patient complications due to fibrotic bridging, excessive scarring and chronic inflammatory reaction.

[278] Owens deposition 09/12/12 273:19 to 274:13; Hinoul deposition 09/18/12 691:24 to 692:5

[279] Hawn MT, Gray SH, Snyder CW, Graham LA, Finan KR, Vick CC. Predictors of mesh explantation after incisional hernia repair Am J Surg. 2011 Jul;202(1):28-33. doi: 10.1016/j.amjsurg.2010.10.011.

[280] Finan KR, Vick CC, Kiefe CI, Neumayer L, Hawn MT. Individual inflammatory response of human blood monocytes to mesh biomaterials Br J Surg. 2003 Jan;90(1):114-20

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VIII. ALTERNATIVE DESIGN

A. Ethicon's development of Polypropylene mesh

1. Ethicon's Prolene Suture

Ethicon's use of polypropylene as a suture material dates to the late 1960's when it began purchasing polypropylene resin for its Prolene sutures from the Montecatini Company at their Novamant Plant in Kenovah, West Virginia. The mixing and compounding of the resin has not changed since that time – same composition; same molecular weight; and same molecular weight distribution. The individual component additives to the resin are Santonox (antioxidant); calcium stearate (lubricant); dilauralthiodipropionate (antioxidant); Procol LA-10 (lubricant); and CPC pigment (colorant to enhance visibility). After the extruded resin material leaves the compounder, it is water quenched, pelletized and airveyored to polyethelene drums for shipping to Ethicon. [290]

2. Ethicon's Hernia Meshes

Over the years, in relation to the manufacture and sale of its polypropylene surgical mesh products, Ethicon has repeatedly claimed in its communications with regulatory bodies, its communications with doctors and patients, and its internal corporate documents (i.e., design verification, etc.) that polypropylene, as a surgical material, is safe in the human body due to its identical composition of a Prolene suture (e.g., In the 510(k) submissions and IFUs, Ethicon states that these surgical mesh products are "constructed of knitted filaments of extruded polypropylene identical in composition to Prolene Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.) This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.")[291]

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According to Ethicon documents regarding the usage of the Prolene suture in Ethicon's surgical mesh and the design evolution of Prolene surgical mesh in various applications and its FDA 510k submissions,[292, 293, 294, 295, 296] Prolene sutures were developed into a flat hernia mesh in 1974 (Prolene "Old Construction, 6 mil" mesh), a modified knit hernia mesh in 1997 (Prolene Rev 2 with a "button hole" pore and a tetrahedral pore), a three-dimensional hernia mesh "system" using Prolene Rev 2 in 1998 ("Prolene Hernia System") and Prolene Mesh Rev 3 in 1999 (5 mil fiber design change). Each of these design versions of Prolene mesh consisted of a heavyweight, small pore, monofilament, polypropylene mesh.[297] [Fig. 21]

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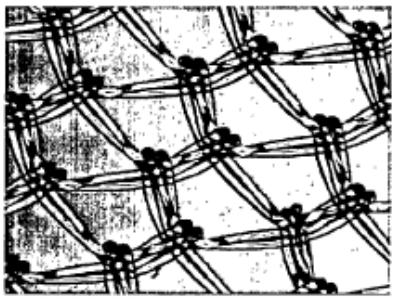
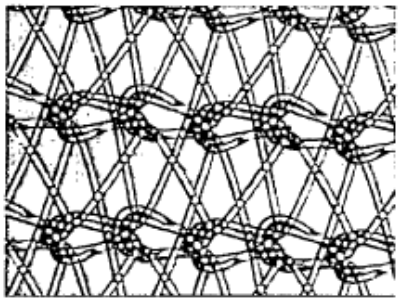
[290] ETH-03883-03885 January, 2003 Report written by John Karl, PE titled "Prolene Resin Manufacturing Specifications" regarding the history of Prolene Sutures
[291] ETH.MESH.00019863 TVT-O 510(k)
[292] ETH.MESH.02227368 Meshes/Devices Chart
[293] ETH.MESH.01816990 Product Development Chart
[294] ETH.MESH.07876572 TVT Secur 510(k)
[295] ETH.MESH.00019863 TVT-O 510 (k)
[296] Tension Free Vaginal Tape 510k
[297] ETH.MESH.00159473; ETH.MESH.09279097

POLYPROPYLENE MESHES

PROLENE Mesh
used in
GYNECARE TVT Tension-free Support for Incontinence
6 mil

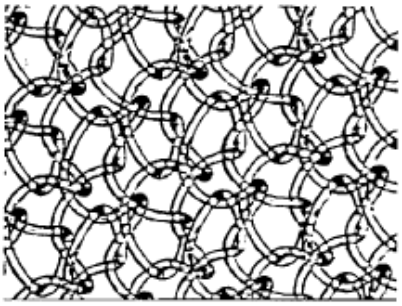


12" x 12" PROLENE
polypropylene Mesh
5 mil

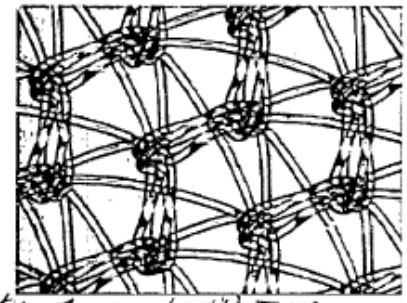


initial caps only

MARLEX* Mesh



PROLENE polypropylene Mesh
used in
PROLENE Hernia System



Capitalized product names are trademarks of ETHICON, INC.
* Marlex is a registered trademark of _____ >

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Figure 21 (Handwriting in Original)

In 1998, with the background of the research done mainly in Aachen and the convincing advantages of large pore constructions, Ethicon began marketing Vypro in Europe for hernia repair. As mentioned above, I raised the idea of a mesh adapted to the physiological requirements in 1993, and was part of the outside research team working with Ethicon to develop Vypro – the first lightweight, large pore, polypropylene mesh. Vypro had an absorbable component, polyglactin-910, which degraded after 90 days, leaving behind less mesh and even larger pores. It was launched by Ethicon in 1998. In 2004 Vypro was replaced by Ultrapro. Ultrapro is the subsequent monofilament variant of Vypro. It is made of monofilament polypropylene fibers with interwoven absorbable Monocryl fibers. Ethicon developed Ultrapro in response to concerns over the multifilament fibers in Vypro, as it was feared by some to be causing an increased risk of infection in some patients. Ultrapro was made with Prolene Rev 4, 3.5 mil fiber and was much lighter than Prolene Soft/Gynemesh PS (25 g/m2 for Ultrapro vs. 45 g/m2 for Prolene Soft) and had much larger pores (5mm for Ultrapro vs. only some pores > 1mm in Prolene Soft).

Ethicon then extended the Prolene line by developing Prolene Soft mesh, which was cleared for marketing in the U.S. in 2000. That same year, the FDA cleared Vypro for marketing in the U.S. as well. Although Prolene Soft mesh was much lighter weight than Prolene (45 g/m2 vs. 105-110 g/m2) and had some pores that were larger than 1 mm diameter (vs. Prolene with zero pores > 1mm), it was still significantly heavier than Vypro (42 g/m2 vs. 25 g/m2) and had much smaller pores (Vypro 3-5 mm diameter).

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Then, in 2002, Ethicon repackaged its Prolene Soft mesh (Prolene Rev 3 with 3.5 mil fibers) as Gynemesh PS and received clearance by the FDA to market it in the U.S. in 2002 for pelvic floor repairs. It was the same mesh material as the hernia mesh, Prolene Soft, and was the first pelvic mesh cleared for marketing in the U.S. for treatment of pelvic organ prolapse. It came in a square sheet, like the hernia mesh version, only smaller, and did not include trocars, cannulas, pre-cut shape, Ethicon-provided professional education, a surgical guide nor a patented technique – all of which would be provided in the Prolift kit a few years later.

In comparison to Vypro and Ultrapro both Prolene and Prolene soft are much heavier and have significantly smaller pores.

3. Ethicon's TVT meshes for Incontinence

In 1997, Ethicon marketed and sold its first mesh for the treatment of stress urinary incontinence (SUI). It used Ethicon's first surgical mesh, Prolene "Old Construction 6 mil" that had been marketed for 23 years. It is known as "TVT Original". Ethicon has continued to use its "Old Construction 6 mil" Prolene mesh in its TVT-O slings (marketed in 2004) and TVT-S (marketed in 2006). Prolene "Old Construction 6 mil" is a heavy-weight (105-110 g/m2) small pore (< 1mm) mesh.

4. Ethicon's Prolapse meshes

In 2005, Ethicon marketed and sold a new pelvic mesh "kit", Prolift. The Prolift "system" contains a mesh that is the same identical mesh as Gynemesh PS and Prolene Soft hernia mesh, but, as mentioned above, it is precut and packaged with surgical tools for placement of the mesh and is inserted pursuant to the patented Prolift procedure.[298]

In 2008, Ethicon marketed and sold a newer version of its prolapse kit – Prolift +M. Prolift +M also used an Ethicon mesh that had been designed for hernia repair, Ultrapro. Again, as with its hernia meshes, Ethicon continued to make its prolapse meshes lighter and its pores larger.[299] However, unlike its hernia meshes and its prolapse meshes, Ethicon chose to never change the mesh material in its TVT slings, opting to stay with the "Old Construction 6 mil" (which, as mentioned, has never changed from 1974 to the present).

In sum, from 1997 to the present, Ethicon's marketing efforts in the U.S. for its surgical meshes for both hernia and pelvic floor application have remained focused on polypropylene as the polymer of choice for these products. With the development of second generation surgical meshes that adapted the "lightweight, large pore" concept to minimize numerous patient complications that accompanied the increased usage of surgical meshes in the 1990's, Ethicon attempted to redesign its hernia and prolapse meshes to make them lighter and with larger pores since 1998.

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In contrast to Ethicon's design changes for its hernia and prolapse meshes, Ethicon has failed to adopt the "lightweight, large pore concept" to make necessary design changes to its TVT incontinence slings, choosing instead to use its first, old construction mesh that they began making in 1974. Literally dozens and dozens of scientific articles since the early 2000's have addressed the need for mesh manufacturers to move ahead with better designed meshes that leave less mesh implanted in the body (lighter weight) and have better tissue integration and less inflammation and scarring in and around the mesh (larger pores).

Ironically, the increasing complications of heavy weight meshes such as Prolene "Old Construction 6 mil" mesh in hernia repair patients in the 1990's was the reason for our Aachen group's development with Ethicon that led to the critical design changes from the heavyweight, small pore construction of Prolene to Vypro and later to Ultrapro. These concepts also led Ethicon to develop its lighter weight, larger pore Prolene Soft/Gynemesh PS in Prolift and Ultrapro in Prolift+M.

So the obvious question becomes "Why did Ethicon adapt the new generation mesh concepts in some of its surgical meshes (hernia and prolapse) but not in others (TVT incontinence slings)?

[298] ETH-65881 Gynecare Prolift IFU
[299] ETH.MESH.00081133 Gynecare Prolift +M IFU

5. A Lighter Weight, Larger Pore Mesh for TVT?

In 2001, Ethicon German scientist, Dr. Bridgette Hellhammer authored an internal document titled "Meshes in Pelvic Floor Repair – Findings from literature review and interviews with surgeons".[300] Her conclusions were that a pelvic floor repair using a mesh implant was plausible, and "A thinner mesh than the current Prolene mesh and with some elasticity would be well accepted. Vypro would meet these requirements. A totally nonabsorbable mesh with similar mechanical properties as Vypro would also be well accepted."[301]

A year earlier, Dr. Hellhammer had polled numerous "key opinion leaders" or KOLs who are top surgeons using Ethicon products and who give feedback to the company regarding different mesh designs that may relate to different mesh-related complications.[302] In her notes generated from the "Pelvic Floor Repair – Surgeon's Feedback on Mesh Concept", Dr. Hellhammer noted the following issues raised by surgeons regarding Prolene/Gynemesh usage versus usage of the lightweight, large pore mesh, Vypro:

Prof. Petri:

- "mesh must be cuttable without fraying."
- "the current polypropylene meshes are considered too thick and too rigid, not only at the edges, but in general. One patient in whom he had used polypropylene mesh for rectocele repair, had experienced an erosion with infection. Therefore, he does not use polypropylene mesh any longer for rectocele repair."
- "He would never use mesh material for anterior vaginal wall repair, because he thinks this is a very delicate area, with the nearness of the bladder neck and a risk of the mesh eroding into the urethra, bladder neck or bladder."

Dr. Fisher:

- "Gynemesh: is perceived as too bulky and rigid. Also, **when cutting the mesh, small particles are released that migrate through the vaginal wall causing pain during intercourse."**
- **"to be improved: the mesh should have minimum retraction when incorporated in the fibrous tissue….Prolene mesh could easily be felt through the vaginal wall by the examiner."**
- "Would healing disturbances total 10% [with Gynemesh]"

Prof. Jacquetin:

- "following Vypro mesh implantation, the patients always had a very soft elastic vaginal wall (which is not so with Prolene mesh which through its stiffness and bulkiness, could easily be felt through the vaginal wall tissue).
- Jacquetin "likes the Vypro mesh, he regards it as much better than Prolene mesh or any other mesh on the market."
- "Patients complain of lateral pains. He thinks that this could be due to

[300] . ETH.MESH.02017169 Hellhammer, B., Meshes in Pelvic Floor Repair – Findings from literature review and interviews with surgeons. (2001)
[301] ETH.MESH.03924557 "Meshes in Pelvic Floor Repair" By Brigitte Hellhammer (6/6/2000)
[302] ETH.MESH.05644163

fixation using the nonabsorable sutures that come under tension while the mesh retracts during tissue incorporation. He also observed this phenomenon with Prolene mesh."

Prof. Falconer:

- "He thinks Vypro mesh could be a good alternative to the present bulky Gynemesh. He sees an advantage in having less foreign body material remaining."

Prof. Cardoza:

- "Mersilene and Prolene meshes both have too sharp edges, according to him."

Dr. Migliori:

- "perceives the bulkiness of the Gynemesh as disadvantageous. The mesh can be felt beneath the vaginal wall.

Prof. Ulmsten:

- "the idea of tension-free mesh is ok, but not optimum"

Prof. Hardiman:

- "carried out a study using Gynemesh for repair of isolated cystocele…20 patients were recruited and operated on. In two patients, [he] observed a wound healing disturbance right in the middle of the vaginal wall wound. The wound did not close above the mesh." (10% erosion). "[L]ikes the Gynemesh, but he thinks a thinner mesh could be more acceptable to surgeons…Vypro or just another thinner mesh such as Soft Prolene Mesh…It is important that the mesh can be cut to individual sizes, **it must not fray nor release particles.**"

Dr. Hilton:

- "he is concerned with using meshes for primary repair, because there is always the risk of erosion or extrusion….Thinner meshes such as Soft Prolene or Vypro would certainly be an improvement to the current Prolene Mesh which is very thick. **[I]t is of utmost importance that the mesh is cuttable and that it does not fray nor release particles after cutting. The small particles migrate and can cause pain during intercourse….the mesh should not roll at the edges."**

Dr. Tunn:

- **"The disadvantage of Prolene mesh he sees is its thickness. One could feel it through the vaginal wall when examining the patients [he] has observed erosions in a number of patients, which he attributes to mechanical irritation of the mesh….biomechanical requirements for a mesh for pelvic floor repair correspond to those of abdominal wall closure, probably even less."**

Dr. Viehout:

- He has used Gynemesh…in 4 anterior repairs, in one he observed an

erosion in the middle of the vaginal incision. Therefore, he would like to know the rejection rates of a new mesh.

- "he favors the Vypro for anterior and posterior repair for its thinness and elasticity. He thinks Gynemesh is too thick and stiff….anything too bulky could have a negative effect on the bladder neck area.

These were not the only top-level, highly-experienced surgeons who were seeing problems with TVT Prolene mesh in pelvic tissues. In 2004, the "TVM Group", who were surgeons working with Ethicon to design a device and a technique that would ultimately become the Prolift kit, indicated that they used Prolene mesh in their first 100 patients but had to abandon it in favor of the lighter weight, larger pore Prolene Soft/Gynemesh PS due to an almost 20% rate of erosions with the Prolene.[303] This experience was recounted again in 2012 in the Clinical Expert Report of Ethicon Medical Director, Piet Hinoul.[304]

With its launch, marketing and sale of Prolift and Prolift+M, Ethicon has intensely and extensively touted the patient benefits of "lightweight, large pore" mesh.[305, 306, 307, 308] In one internal PowerPoint during the transition from using Prolene Soft mesh in its prolapse kit, Prolift, to using Ultrapro in its prolapse kit, Prolift+M, a top Ethicon R&D manager, Cliff Volpe put it this way: [309]

- "Pore size…'the greater distance between pores resists the ability of 'bridging fibrosis', contributing to improved compliance and less passive compression of Biomaterial"

In a similar internal Ethicon presentation entitled "Stand and Deliver", the benefits of lightweight, large pore meshes was presented like this:[310]

- "Improved Tissue Response"
- "Resists Bridging Fibrosis"
- "…improved integration into surrounding tissue in humans"
- "Lightweight mesh has demonstrated less inflammatory response and reduced shrinkage"

Two more Ethicon scientists, Joerg Holste and Boris Batke had internal Ethicon PowerPoint presentations in which these concepts and the basis for them were expressed:

- "improved patient comfort"
- "Less 'residual Foreign Body' implanted over the life of the patient"
- "A secure repair" [311]

[303] ETH.MESH.00659678 The TVM Group, "Conceptual advances in the surgical management of genital prolapse" article
[304] ETH.MESH.08315779 Piet Hinoul Clinical Expert Report Gynecare Prolift +M Pelvic Floor Repair System
[305] ETH-65881 Gynecare Prolift IFU
[306] ETH.MESH.00748451 Prolift & Prolift +M 510k
[307] ETH-10187 Prolift Patient Brochure
[308] ETH.MESH.02341954 Prolift & Prolift +M Patient Brochure
[309] ETH.MESH.00237968 "R&D Perspective – The Journey from Prolift to Prolift +M" PowePoint presentation by Cliff Volpe
[310] ETH.MESH.00006796 Stand and Deliver powerpoint

- "Less Remaining foreign body material"
- "Large pore size > 2.5 mm"
- "Thin Filaments" [312]
- "low mass volume & small surface – mild tissue reaction, mild inflammation, less scar formation" [313]

Both of these scientists testified at their depositions that the "Old Construction 6 mil" Prolene mesh used in all of Ethicon's TVT devices is heavyweight and small pore. [314] [315]

As was stated by Dr. Holste in an internal Ethicon email dated March 13, 2006, "Basically small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage…"[316] Yet, despite this knowledge throughout the ranks of the Ethicon scientists and medical personnel, they continued to manufacture the TVT products with first generation, Old Construction mesh.

In an Ethicon presentation entitled "FDA Review – R&D" on a slide entitled "SUI Sling Innovation", Ethicon states its knowledge of the need to develop new materials for its TVT slings. They list a whole host of adverse events associated with their meshes for pelvic tissues like: hematoma, infection, pain, dyspareunia and erosion and in the "notes" field, they say that they are looking for a "new material that could better deliver the biomechanics that are needed with as little implant material as possible."[317]

In an "Invention Disclosure" by two of Ethicon's top mesh scientists, Juergen Trzewik and Peter Meier, again the benefits of lightweight, large pore meshes are discussed as well as the risks of its heavyweight, small pore predecessor: "A reduced mesh pore size (< 1mm) is identified as a major cause of 'bridging fibrosis' causing reduced tissue compliance in the area of the mesh implants." [318]

In still other Ethicon documents, Dr. Trzewik lists the "Target" characteristics of its surgical meshes and in the comparison grid, Prolene fails, in comparison to Vypro and Ultrapro, to meet numerous "Target" characteristics like pore size, porosity, area weight, thickness, and warp forces.[319]

In a 510k submission by Ethicon to the FDA in 2010, Ethicon sought clearance to sell and market "TVT-O PA".[320] As with their decision to design down the weight and increase the pores from Prolene to Prolene Soft to Ultrapro for hernia, and from Prolene to Gynemesh PS/Prolift to Prolift+M for prolapse, consideration was given by Ethicon to using Ultrapro for TVT. Other

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[311] 2011 Ethicon Polypropylene Mesh Technology March 2011 Adelaide
[312] ETH.MESH.05479411 "The (clinical) argument of lightweight mesh in abdominal surgery" by Boris Batke
[313] ETH.MESH.04941016 Lightweight Mesh Development
[314] Batke deposition 08/01/2013 104:4 to 11
[315] Holste deposition 07/29/2013 62:21 to 63:1
[316] ETH.MESH.05446127 3/13/06 Holste, Dr. Joerg to Engel, Dr. Dieter; Manley, Quentin; Storch, Mark L. SUBJECT: AW: Mesh and Tissue Contraction in Animal
[317] ETH.MESH.03032928 FDA Review R&D
[318] ETH.MESH.09651393 Invention Disclosure
[319] ETH.MESH.09671620 Weights, elasticity chart
[320] ETH.MESH.03658980 TVT-O PA 510k

internal Ethicon documents also address changing TVT from Prolene to a partially-absorbable mesh like Ultrapro/Prolift+M. Scientifically, this would make sense given that the forces in the abdomen are much greater than those in the pelvic tissues under the bladder neck. (See references in "Muehl Testing" section above.)

Despite having meshes that are designed with newer generation technology and considerations, Ethicon, to my knowledge, has never commercialized Prolene Soft, Ultrapro or any other lighter weight, larger pore mesh than Prolene in its TVT devices despite abundant evidence that there were those within Ethicon who understood the patient consequences of not replacing the Prolene mesh in TVT with a safer alternative mesh.

It is my opinion, to a reasonable degree of medical and scientific certainty, that the weight and pore size of TVT "Old Construction" 6 mil Prolene mesh creates a significantly greater risk in a woman's pelvic tissue of greater inflammatory response due to an unnecessarily high weight, a significantly increased risk of fibrotic bridging and poor tissue integration due to the size of the pores and thus, a significantly increased risk of scar plate formation and encapsulation of the mesh in scar tissue, increased risk of mesh contraction, nerve entrapment, chronic pelvic pain, erosions, dyspareunia, recurrence and need for reoperation, than lighter weight, larger pore meshes.

Based on these characteristics of TVT Prolene mesh, my studies comparing Prolene mesh to meshes of different, Ethicon's internal documents and other scientific literature, as well as my background, training and experience over 30 years, meshes with a weight of approximately 25 g/m2 and pore size of > 1mm diameter with <10 % elasticity at 16N/cm would be a safer alternative mesh material for human tissues than Ethicon's TVT Prolene mesh.[321]

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6. A Different Material (PVDF) for TVT?

In 2000, Ethicon received 510(k) clearance for a suture with a material different from its polypropylene Prolene suture. The product name was "Pronova", which is made of a copolymer of polyvinylidene fluoride (PVDF).[322]

In fact, in 1998 with the support of the IZKF BIOMAT of the Aachen University I started a research project to develop a monofilament mesh made of pure PVDF, as it was suspected to be the best polymer available at that time. This application was presented to Ethicon; however any collaboration in this project was rejected. Surprisingly we just received a Pronova mesh for testing in an animal experiment, which not surprisingly showed a better performance than the standard of a heavy weight material – Prolene. The results were presented to Ethicon in 2001 and were published in 2002.[323] However any further collaboration with Aachen to develop meshes of PVDF has been ended by Ethicon with the comment that there was no interest to replace the polypropylene.

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[321] Klinge U, Binneboesel M, Kuschel S, Schuessler B. Demands and properties of alloplastic implants for the treatment of stress urinary incontinence. Expert Rev Med Devices. 2007 May;4(3):349-59.
[322] ETH.MESH.01819833 "Pelvic Floor Repair Platform" Slide 35
[323] PVDF as a new polymer for the construction of surgical meshes. Klinge U, Klosterhalfen B, Ottinger AP, Junge K, Schumpelick V. Biomaterials. 2002 Aug;23(16):3487-93)

However, in 2002, Ethicon obtained a German patent No. DE 10043396C1 20.06.2002 for a PVDF surgical implant, including requirement of pore sizes of > 1.5 mm.[324] The advantage of a PVDF device was explained by studies.[325] Studies, including some of which I have published, have shown that this material has improved textile and biological properties.[326, 327] It is thermally stable and more abrasion resistant than other flouroplastics. PVDF sutures are routinely used in cardiovascular and orthopaedic surgery.[328] It induces a minimal cellular response, shows exceptional chemical stability and has excellent resistance to aging.

In an email from a top Ethicon German scientist in 2007 regarding internal reaction to recently-published literature concerning degradation of polypropylene meshes in human tissue explants, Dr. Dieter Engel stated, "What is the future? We will change the material of our mesh and move to Pronova as the future material platform for mesh…Pronova has a reduced foreign body reaction compared to Prolene, as shown in several animal studies, and will improve the perceived biocompatibility of our mesh. Besides, Pronova is much less susceptible to mechanical damage…it is much easier to process in the knitting machines, less quality issues."[329] Unfortunately, this "future" has never become a reality at Ethicon.

Ethicon also had a renewed interest in trying to develop Pronova (PVDF) sutures as a prolapse mesh. As a result, they began a new project to investigate this PVDF PFR design concept through a new project dubbed by Ethicon as "Project Thunder". August 14, 2007 Project Thunder meeting minutes reported that Ultra-light polypropylene mesh was ready, Pronova in process. Pros and cons of Pronova to polypropylene: Pro: Softness, Elasticity, better biocompatibility, less "aging" long time breakage, easier to manufacture and sterilize. Con: "May be more expansive [sic]".[330]

As per an Ethicon internal PowerPoint presentation, sometime during the period from November 2010 to October 2011, Project Thunder was "killed" due to "tech push".[331] Although it is unclear as to what "tech push" infers, in multiple places, Ethicon seems to focus on the fact that PVDF costs more than polypropylene.[332, 333] In their May 9, 2008 Thunder MGPP presentation, one slide is particularly telling. It shows the PVDF products all out-performing Ethicon's polypropylene meshes in every design attribute except one…cost.[334] Project Thunder was "killed" by Ethicon despite the fact that at multiple meetings, it was described as the "holy grail" of pelvic floor meshes, the first "patient-centric" mesh, the first Ethicon mesh actually

[324] German Patent No. DE10043396C1 20.06.2002; Certified Translation of Patent
[325] German Patent No. DE10043396C1 20.06.2002; Certified Translation of Patent
[326] Klinge U, Klosterhalfen B, Ottinger A, Junge K, Schumpelick V. PVDF as a new polymer for the construction of surgical meshes. Biomaterials 2002; 23:3487-3493
[327] Klink C., Junge, J., Binnebosel., Alizai, H., Otto, J., Neumann, U., Klinge, U. Comparison of Long-Term biocompatibility of PVDF and PP meshes. Journal of Invetigative Surgery (2011); 24:292-299
[328] Laroche G, Marois Y, Guidoin R. Polyvinylidene fluoride (PVDF) as a biomaterial: from polymeric raw material to monofilament vascular suture. J. Biomed. Mater. Res. 1995; 29:1525-1536
[329] ETH.MESH.05447475 Email from Dieter Engel to John Gillespie et al. re How inert is polypropylene?
[330] ETH.MESH.00869908 Thunder Meeting Minutes dated 8/14/07
[331] ETH.MESH.00562421 untitled PowerPoint update from November 2010 – October 2011
[332] ETH.MESH.02227224 PowerPoint Presentation dated 05/09/08 titled MGPP Thunder Decision Meeting
[333] ETH.MESH.00869908 Thunder Meeting Minutes dated 8/14/07
[334] ETH.MESH.02227224 PowerPoint Presentation dated 05/09/08 titled MGPP Thunder Decision Meeting

"designed for the pelvic floor" and explained that it would address the issue of all Ethicon's previous meshes that were "overengineered". [335]

It has been found in literature that polypropylene degrades and PVDF does not. This can be found in numerous articles, by numerous authors. Numerous other articles have demonstrated the superior benefits of PVDF in tissue. [336, 337, 338, 339, 340]

The characteristics of implanted polyvinylidene fluoride and polypropylene sutures used in vascular surgery were analyzed in 1998 by Celine Mary et al. They found that after periods of 1 and 2 years there was little to no sign of surface cracking of polyvinylidene fluoride whereas explanted polypropylene sutures showed visual evidence of surface stress cracking. The authors concluded that the PVDF likely has superior biostability to polypropylene over the long term. [341]

Klink et al. compared the performance of PVDF and polypropylene meshes. The SEM data clearly suggests degradation on the part of polypropylene mesh with virtually none found in the PVDF mesh after implantation in rats. They concluded that PVDF meshes show low inflammation and mature scar formation after six months and that PVDF would be a possible alternative to polypropylene mesh implants. [342]

In fact, even in Ethicon's own 7-year dog study, it was found that after seven years, Ethicon's Prolene sutures showed progressive degradation, while PVDF sutures show none. [343]

7. *Dynamesh - FEG*

From our published study in 2013, we found that the textile porosity of the center of another surgical mesh for pelvic floor repair, Dynamesh (made of PVDF), known to incites a less intense FBR than polypropylene, and thus requires lower effective porosity to prevent bridging fibrosis, was 63.3+/- 0.6 %, whereas the effective porosity was 56.5 +/-1.2 %. The minimal difference between textile and effective porosity reflected the fact that most pores had a diameter of larger than 600 µm (the minimum distance between filaments to calculate effective pore areas, and thus the effective porosity, of polypropylene is 1000 µm and 600 µm for PVDF). The elongation was more when tension was applied in the cross direction (9% at 4.9 N/cm) vs. the warp direction

[335] ETH.MESH.00562421 untitled PowerPoint updated from November 2010-October 2011
[336] Klink C., Junge, J., Binnebosel., Alizai, H., Otto, J., Neumann, U., Klinge, U. Comparison of Long-Term biocompatibility of PVDF and PP meshes. Journal of Invetigative Surgery (2011); 24:292-299
[337] Silva, R., Silva, P., Carvalho, M. Degradation Studies of Some Polymeric Biomaterials: Polypropylene (PP) and Polyvinylidene Difouride (PVDF). Material Science Forum (2007); 593-543
[338] Conze, J., et al., New polymer for intra-abdominal meshes--PVDF copolymer. J Biomed Mater Res B Appl Biomater, 2008. 87(2): p. 321-8.
[339] Klinge U, Klosterhalfen B, Ottinger A, Junge K, Schumpelick V. PVDF as a new polymer for the construction of surgical meshes. Biomaterials 2002; 23:3487-3493
[340] Laroche G, Marois Y, Guidoin R. Polyvinylidene fluoride (PVDF) as a biomaterial: from polymeric raw material to monofilament vascular suture. J. Biomed. Mater. Res. 1995; 29:1525-1536
[341] Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206
[342] C. D. Klink, K. Junge, M. Binnebosel, H. P. Alizai, J. Otto, U. P. Neumann, U. Klinge, Comparison of Long-Term Biocompability of PVDF and PP Meshes, *Journal of Investigative Surgery*, 24 (2011) 292-299.
[343] ETH.MESH.09557798 7 Year Dog Study

(4% at 4.9 N/cm). At a strain of 4.9 N/cm in the cross direction, the textile porosity decreased only slightly to 62.7%. The effective porosity at that strain decreased only to 54.7%. In the warp direction the textile porosity decreased to 59.9% at 4.9 N/cm and the effective porosity to 52.5%.[344]

Dynamesh has a symmetrical shape. The arms are oriented in the same direction in reference to the mesh structure. Therefore, only one arm (Arm 1) was measured and taken as representative for all four arms. At 4.9 N/cm of force, the arm maintained 60.8% textile porosity and 54.6% effective porosity.

Overall, the alternative textile structure showed remarkable effective porosity and high effective porosity persisting even under strain whether the measurements were taken in the center portion of the prosthetic or in the arm. It also showed roughly equivalent performance under strain whether being tensed in the warp or cross direction. In sum, Dynamesh (PVDF) showed excellent structural stability under tension and excellent effective porosity to resist fibrotic bridging. Another significant observation of the Dynamesh product is that unlike Prolift, Dynamesh has a smooth seam around the entirety of the mesh with no fraying at the edges nor curling in the arms under strain as was seen with both of the Ethicon products.

At his deposition, Joerg Holste was asked about Ethicon activities involving comparing their products to Dynamesh. According to Ethicon documents, they were looking at FEG's website and trying to determine if they could disprove any of FEG's claims regarding their meshes, including Dynamesh. Ethicon field representatives in Brazil were so concerned about the competition by Dynamesh sling products in that country that in 2009, they were sending emails regarding how to disparage FEG's product to keep them from using Dynamesh. [345]

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There are alternative design characteristics of pelvic floor meshes that would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT.

One such safer alternative design would be a mesh product with larger pores (> 1mm in diameter after accounting for reasonable implantation and in vivo forces) and lighter weight (closer to their Ultrapro mesh which is 25 g/m2). Ethicon has developed a number of meshes for hernia repair and for prolapse repair which are at least closer to fulfilling these requirements. However, even with larger pores and less weight, the knitted structure design would require greater stability, both short and long term, to resist curling, roping, fraying and particle loss. Structural stability under strain and a mesh with finished edges (seam) would be safer than the Prolene mesh.

Another safer design would be a polymer that better resists degradation and elicits a more favorable inflammatory response. PVDF, as a synthetic, non-absorbable suture or mesh material has improved textile and biological properties over polypropylene. It is thermally stable and more abrasion resistant than other flouroplastics and induces a minimal cellular response, shows

[344] Otto, J., Kaldenhoff, E., Kirschner-Hermanns, R., Muhl, T., Klinge, U. Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates. Wiley Online

[345] ETH.MESH.04066979 Email re Dynamesh in Brazil

exceptional chemical stability and has excellent resistance to aging. Based on these characteristics, my studies comparing PVDF to polypropylene, Ethicon's internal documents and other scientific literature, as well as my background, training and experience over 30 years, it is my opinion, to a reasonable degree of medical and scientific certainty, that PVDF, in the appropriate design, is a safer alternative mesh material for human tissues than Ethicon's TVT Prolene mesh.

IX. SUMMARY OF OPINIONS

The following opinions are stated to a reasonable degree of medical and scientific certainty:

Prior to launching their first surgical mesh for gynecological repair, TVT for sale in the U.S., and according to their own documents, Ethicon was aware of the most important design requirements for a safe pelvic floor mesh product.

According to their documents, Ethicon also knew why these design requirements were so important in terms of patient safety. However, as is also stated in their documents, Ethicon was aware of the challenges and uncertainties of designing a safe mesh for the pelvic floor; that the design of their pelvic floor meshes, including TVT, did not meet all their claimed optimal design requirements; and, that as a result, this led to patient complaints and complications.

Ethicon has a long history of manufacturing surgical meshes that are intended to be permanently implanted by doctors in patients' bodies. They likewise have a long history of reported complications with their prosthetic meshes. With their experience from complications associated with some of the poor design characteristics in hernia meshes, Ethicon knew that poor design leads to poor outcome.

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Through my team's collaborative efforts with Ethicon in the late 1990's and early 2000's, Ethicon learned that the development of an optimal surgical mesh design for any application has to consider first, the polymer; second, the biomechanics (physiological requirements) as to strength, elasticity and structural stability; and third, the structure of the device in terms of geometric design, knitting characteristics, fiber size and pore size. Ethicon knew that the result of these design considerations and choices would influence the tissue reaction, primarily the intensity of the inflammatory and fibrotic response, thereby directly affecting the biocompatibility of the device and thus the clinical outcome.

However, despite this knowledge, Ethicon failed to appropriately design and test TVT to determine if these unintended and adverse events would occur when implanting it permanently into a woman's pelvic tissues resulting in significant morbidity to women around the world.

Ethicon has stated repeatedly in its documents that it had a very poor understanding of the biomechanics of the pelvic floor, which apparently continues to this day. As such, they were not able to establish reliable parameters for the design of the device. Furthermore, despite Ethicon's apparent knowledge of the significant amount of mesh shrinkage experienced by patients in whom the TVT is implanted, the potential causes of mesh shrinkage, as well the resultant patient complications that could occur as a result of this shrinkage, they did no testing nor made any

design changes to TVT in order to reduce the occurrence of this known and serious complication. Failure by Ethicon to act as a reasonable manufacturer and to properly study and/or make the necessary design changes to avoid this and the other safety hazards mentioned in this report was improper, irresponsible and threatened patient safety.

I reserve the right to modify these opinions as necessary based upon any new or additional information or data that I may obtain or with which I am presented including, without limitation, any materials that I produce in response to Ethicon's requests.

X. EXHIBITS

My current curriculum vitae is attached as Exhibit "A"

All exhibits that will be used to support my finding and opinions are included above and listed below in Exhibit "B"

Attached as Exhibit "C" are the histopathological images for each explant specimen.

Attached as Exhibits "D" is a grid of identifying information for the explant specimens.

XI. RECENT TESTIMONY

I have testified as an expert at the following trial:

Linda Gross, et al. vs. Gynecare, et al.; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08

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XII. COMPENSATION

I am compensated for investigation, study and consultation in the case at the rate of $500.00 per hour.

This 13 day of October 2013

Prof. Dr. med. Uwe Klinge

EXHIBIT

A

CV Professor Dr. med. Uwe Klinge

Born at 30.4.1959 in Wilhelmshaven, Germany

Primary, secondary, high school 1964-1977 Wilhelmshaven
Medical school 1977-1983 RWTH Aachen

Medical profession

12/1983 – 2/85:	military service VKK 321, Düsseldorf
1.3.1985:	surgical resident ship at the Surgical Department of the University Hospital at the RWTH Aachen (Head Prof. Reifferscheidt, after 12/85 Prof. Schumpelick, after 3/2010 Prof. Neumann)
1992:	Thesis at the Department for biochemistry, Prof. Gersonde at 29.4.1985 „In-vitro investigation of the oxygen binding curve of human erythrocytes in the presence of glucose and insulin “
15.12.1993:	Specialist for general surgery
since 15.10.1999:	Oberarzt of the surgical Department
1/2000	Venia legendi for Surgery, Habilitation with the title „Use of alloplastic meshes for the repair of abdominal wall hernia: optimisation by adjustment to the physiological requirements “
Since 15.10.2000:	Principal investigator of the surgical department
21.3.2002:	specialist for surgical intensive care medicine
1.1.2003 – 1.11.2006:	Assistant medical director
21.7.2004:	Specialist for visceral surgery
13.12.2005:	appointment as a.pl. Profess
1.11.2006-28.2.2009:	Cooperation with the Institute for applied medical engineering of the Helmholtz institute

1. Scientific work

- Pathophysiology and treatment of abdominal wall hernia
- Biomaterials and tissue response
- Impact of altered ECM for wound healing and cancer development
- Analysis of biological networks
- Identification of prognostic markers
- Optimisation of staplers

Member of the Editorial Board of World Journal of Gastrointestinal Surgery (WJGS)
Member of the scientific committee for the research program START of the university clinic
Member of the German Society of surgeons
Member of the European Hernia Society
Member of the German Hernia Society

Publications

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26. U.Klinge Langzeitbeatmung und Entwöhnung Intensiv-Workshop 1994
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Oral presentation, on invitation:

1. U.Klinge Review of literature and experimental results of mesh surgery Expert-Meeting Suffretta-House St. Moritz Feb. 1994
2. U.Klinge Pathophysiologie der Narbenhernie Chirurgentag Nürnberg 24.10.1996
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4. U. Klinge, B Klosterhalfen (1998) Biocompatibility of biomaterials – experimental aspects. II Suvretta meeting: abdominal wall: function, defects and repair. 8.-14.3.1998 St. Moritz Swiss
5. B. Klosterhalfen, U. Klinge (1998) Biocompatibility of biomaterials – histological aspects. II Suvretta meeting: abdominal wall: function, defects and repair. 8.-14.3.1998 St. Moritz Swiss
6. U. Klinge (1998) Meshes zur Hernienreparation. 7. Interdisziplinäres Forum der Förderation operativer medizinisch-wissenschaftlicher Fachgesellschaften 17.10.1998 Wiesbaden
7. U. Klinge (1999) Chirurgie der Narbenhernie. 5. Kölner Tagung ambulantes Operieren. Köln, 7.5.1999
8. U. Klinge (1999) Pathophysiologie der Bauchdecke. Weißenseer Operationskurs 24.9.99
9. U. Klinge (1999) Rezidive und Patientenkomfort im Langzeitverlauf. Weißenseer Operationskurs 24.9.99
10. U. Klinge (7.12.1999) Meshes in der Hernienchirurgie. 5. Zürser Hernienforum, Zürs, Austria
11. U. Klinge (9.3.2000) Narbenhernienchirurgie: Primärverschluß oder Netzimplantat? Interdisziplinäre Viszeralchirurgie am Inselspital, Bern, Schweiz
12. U. Klinge (3.5.2000) Biomaterialien in der Hernienchirurgie. FomwF, 117. Kongreß der Deutschen Gesellschaft für Chirurgie 2.-6.5.2000, Berlin
13. U. Klinge (4.5.2000) Epidemiologie und Pathophysiologie der Bauchwanddefekte. Narbenhernie, 117. Kongreß der Deutschen Gesellschaft für Chirurgie 2.-6.5.2000, Berlin
14. U. Klinge (26.5.2000) Anatomy and physiology of the abdominal wall. Laparoscopic incisional hernia repair a standard therapy? Rastatt, 25.5-27.5.2000
15. U. Klinge (2.6.2000) Technical aspects, abdominal wall physiology, integration and inflammatory reaction. 35. ESSR-Kongreß, Malmö, 1.-3.6.2000
16. U. Klinge (2.6.2000) News and future outlooks. 35. ESSR-Kongreß, Malmö, 1.-3.6.2000
17. U. Klinge (2000) Pathophysiologie der Bauchdecke. Weißenseer Operationskurs 2000, 8.9.2000, Berlin
18. U. Klinge (2000) Rezidive und Patientenkomfort im Langzeitverlauf. Weißenseer Operationskurs 2000, 8.9.2000, Berlin
19. U. Klinge (2000) Netzimplantate in der Hernienchirurgie – Charakteristika und Anforderungen.Netzimplantate 22.-23.9.2000, Würzburg
20. U. Klinge (2000) Minimierte Polypropylen-Netze zur präperitonealen Netzplastik – prospektive Studie. 22.-23.9.2000, Würzburg
21. U. Klinge (2000) Implantierbare Netze in der Chirurgie – Nutzen oder Risiko? Fortbildungsveranstaltung der Kreisstelle Mülheim/Ruhr 10.10.2000, Evang. Krankenhaus Mülheim a. d. Ruhr
22. U. Klinge, B. Klosterhalfen, V. Schumpelick (2000) Kollagenstoffwechselstörungen und Konsequenzen für die chirurgische Therapie. Gründungskongress der Arbeitsgemeinschaft Wundheilung der DGfC, 13-14.10.2000 Tübingen
23. U. Klinge (2000) Offene Mesh-augmentierte Reparationsverfahren der Leistenhernie. 12. Wuppertaler Workshop für laparoskopische Operationen, 16.-17.11.2000, Wuppertal

24. U. Klinge (2001) Netzimplantate in der Hernienchirurgie: Charakteristika und Anforderungen. Implantate in der Hernienchirurgie – Quo vadis? 2.-4.4.2001, European Surgical Institute, Norderstedt
25. Klinge, U (2001) Rezidivoperationen und Biomaterial. 1668. Jahrestagung der Vereinigung Niederrheinsich-Westfälischer Chirurgen, 27.-29.9.2001 Bielefeld
26. Klinge, U (2001) Rezidive und Patientenkomfort im Langzeitverlauf. 3. Weißenseer Operationskurs 28.-29.9.2001, Berlin
27. Klinge U (2001) Welcher Patient bekommt ein Rezidiv? Aktueller Stand der Forschung. Workshop Viszeralchirurgie 24.-26.10.2001
28. Klinge U (2002) Epidemiologie, Pathologie und sozioökonomische Bedeutung der Narbenhernie. Baden-Baden 21-23.2.2002: Symposium Laparoskopische und konventionelle Narbenhernienreparation. Konkurrierende oder ergänzende Verfahren?
29. Klinge U (2002) Shouldice Methode der Wahl? Symposium 20.4.2002, European Surgical Institute, Norderstedt
30. Klinge U (2002) Pathophysiological concept for hernia repair. ESSR Congress Szeged, 23.-25.5.2002
31. Klinge, U (2002) Der Shouldice. 18. Krefelder Chirurgen-Symposium, 12.6.2002, Krefeld
32. Klinge U (2002) Die parastomale Hernie – seine Ursachen und Möglichkeiten der Therapie. ILCO Aachen, 26.8.2002, Aachen
33. Klinge, U (2002) Impact of mesh material on clinical results. III Spotkanie Polskiego Klubo Przepuklinowego 20.-21.9.2002, Bydgoszczy, Poland
34. Klinge U (2002) Epidemiologie und Pathogenese der Narbenhernie sowie Ansätze zu deren Reparation. 2. Österreichischer Chirurgentag, Baden, 22.-23.11.02
35. Klinge U (2003) How to construct a mesh? III. Suvretta meeting 14.-18.1.2003-01-22
36. Klinge U (2003) Mesh materials: tissue response and tissue engineering. ESAO 3.9-6.9.2003, Aachen
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38. Klinge U (2004) Spätfolgen und –ergebnisse nach Netzimplantation in der Bauchdecke. 10. 10. Kölner Tagung des BDC „Ambulante Chirurgie in Klinik und Praxis“, 14.-15.5.2004, Köln, Crowne Plaza Hotel
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40. Klinge, Uwe (2004) Vorteile der konventionellen Hernienchirurgie. Marburg, 30.6.2004
41. Klinge, Uwe (2004) Das Netz als Gewebeersatz. 2. Mitteldeutscher Chirurgenkongress, Leipzig 23.-25.9.2004-09-27
42. Klinge U (2004) Pathophysiology and therapeutic impact of meshes. Utrecht 13.9.2004
43. Klinge U (2004) Biomaterials for Hernia repair. Utrecht 13.9.2004
44. Klinge U (2004) Standardoperationen – unterer GI-Trakt. Workshop Praktische Onkologie, Bonn 23.-24.10.2004
45. Klinge U (2004) Standardoperationen – oberer GI-Trakt. Workshop Praktische Onkologie, Bonn 23.-24.10.2004
46. Klinge U (2004) Novel textile structures in medicine. 31th Aachen Textile conference, 24.-25.11.2004, Aachen, Eurogress
47. Klinge U (2.1.2005) Complications in open incisional hernia, European hernia symposium, London
48. Klinge (2.1.2005) Evidence based open IH, European hernia symposium, London
49. Klinge, U (2005) Nabel-, Narbenhernie. BDC-Seminar, Kassel, 14.-18.2.2005
50. Klinge, U (2005) Open-Non-Mesh: Shouldice – the good old way. 16.2.2005 Leistenhernienchirurgie 2005, Bethlehem-Krankenhaus, Stolberg

51. Klinge U (2005) Alloplastische Implantate und Gewebereaktion. Luzern 22.9.2005 1. gemeinsame Fortbildung der Vereinigung der Gynäkologen Luzern/Zentralschweiz
52. Klinge U (2005) Standardoperationen – unterer GI-Trakt. Workshop Praktische Onkologie, Bonn 14.-16.10.2005
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54. Klinge U (2005) Narbenhernien – nur bei den anderen? State of the art lecture. 16. Berner Symposium, Bern 4.11.2005
55. Klinge (2006) Rezidivhernien – ein biologisches Problem? 123. Kongress der DGfC, Berlin 2.-5.5.2006
56. Klinge (2006) Modern hernia repair. Workshop Prof. Berger, Baden-Baden 28.4.2006
57. Klinge (2006) Komplikationen der minimal-invasiven Hernientherapie. Mic-Club West, Dinslaken, 19.5.2006
58. Klinge (2006) Auswahlkriterien für Netze. Hernienchirurgie 2006. Deutsche Herniengesellschaft Hannover 26.-27.5.2006
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60. Klinge U (2006) Pathohistological data of meshes. 10th world congress of endoscopic surgery, Berlin 13.-16.9.2006
61. Klinge U (2006) Technical and biological aspects of meshes. 10th world congress of endoscopic surgery, Berlin 13.-16.9.2006
62. Klinge U (2006) Narbenhernie: chirurgische Fehler oder Schicksaal? Gastroenterologie 2006, 13.-16. September 2006, Hannover
63. Klinge U. Anatomical limitation for mesh positioning. 2nd Congress of the Asia pacific hernia society 2006, 6-8th October
64. Klinge U Recurrence as a problem of biology & collagens. 2nd Congress of the Asia pacific hernia society 2006, 6-8th October
65. U. Klinge Standardoperationen bei Tumoren des unteren GI-Traktes. Inderdisziplinärer Workshop GI Tumore. 20-12.10.2006, Bonn
66. U. Klinge Standardoperationen bei Tumoren des oberen GI-Traktes. Inderdisziplinärer Workshop GI Tumore. 20-12.10.2006, Bonn
67. Klinge U. Meshes in der Chirurgie. Berlin 4.11.2006 Uro-gynäkologische Tage
68. Klinge U: Biomaterialien für die Hernienchirurgie: für wen, wie und wieviel? Berliner Hernien-Tage 18-20.1.2007
69. U. Klinge Der chronische Leistenschmerz. 4.5.2007. Jahreskongreß der DGfC
70. U. Klinge The concept of flat meshes. 8.8.2007, Shanghai
71. U. Klinge How to prevent recurrences. 8.8.2007, Shanghai
72. U. Klinge Standardverfahren oder maßgeschneiderte Therapie – wo soll die Reise hingehen? Herbstkongreß der DGVC vom 12. bis 15.09.2007, Bochum
73. U. Klinge Evidence-basierte Datenlage zur chirurgischen Narbenhernien-Versorgung. Herbstkongreß der DGVC vom 12. bis 15.09.2007, Bochum
74. U. Klinge Was sind die Probleme mit schwergewichtigen Netzen? Herbstkongreß der DGVC vom 12. bis 15.09.2007, Bochum
75. U. Klinge Meshes in der Chirurgie, Hamburg ESI Mesh-Forum 17.9.2007
76. U. Klinge Update Hernienchirurgie, Freiburg, 8.10.2007
77. U. Klinge: Does material and porosity of meshes matter? 8th congress of the panhellenic surgical society of northern Greece, 18-21.10.2007, Thessaloniki
78. U. Klinge: Concept of CRPS in the groin, and strategies for treatment. Pain & Hernia surgery symposium, ESI, Hamburg, 30th October 2007
79. U. Klinge: The CRPS – concept for chronic pain in the groin? Rotterdam Interactive Congress on Hernia RICH 2007, 16.11.2007, Rotterdam

80. U. Klinge: The CRPS as concept for chronic pain? Belgium surgical society 2007, 29.11.2007, Brüssel
81. U. Klinge: Was können Goldstandards leisten? 14.12.2007 Berlin, http://www.gcp-workshop.de/1331.html
82. U. Klinge: Concept of complex regional pain syndrome in the groin and strategies for treatment. 3rd annual meeting of IEHS 17.-19.1.2008 Stuttgart
83. U. Klinge Polyester, PVDF oder PTFE – kein, zwei oder vier Fluoratome? 2. Berliner Hernientage 25.-26.1.2008 Berlin
84. U. Klinge Schluß mit der Suche nach dem Gold-Standard! 2. Berliner Hernientage 25.-26.1.2008 Berlin
85. U. Klinge: Experimentelle Untersuchungen zu alloplastischen Materialien:Welche Eigenschaften sollten sie für die Verwendung am Beckenboden haben? 17. Urolog. Winterworkshop Leogang 28.01. - 01.02.2008
86. U. Klinge: Die Chirurgie der Leistenhernie – von der Stange oder nach Maß? Fortbildungsveranstaltung der AEKNO, Kreisstelle Dusiburg 20.2.2008
87. U. Klinge: Experimental investigations with alloplastic materials: Which properties are essential for use at the pelvic floor? International collaboration of the pelvic floor ICOPF
88. U. Klinge: Welche Hernie braucht ein Mesh? 1. Tagung der Schweitzer Herniengesellschaft in Bern, 4.4.2008
89. U. Klinge: Welche Probleme können bei der Verwendung von Netzen in der Hernienchirurgie auftreten? 125. Kongress der DGfC, 22.-25.4.2008, Berlin
90. U. Klinge : Low-weight polypropylene mesh: what is the clinical importance of the porosity for hernia repair? 30. congreß of the EHS, Sevilla, Spain: 7-10.5.2008
91. U. Klinge: Grundlagen der Hernienreparation aus Sicht des wissenschaftlichen Chirurgen. 5. Tagung der Deutschen Hernien-Gesellschaft, Baden-Baden:29.-31.5.2008
92. U. Klinge: Postoperative CRPS in inguinal hernia patients. 5. Suvretta-Workshop, St. Moritz: 1.-7.7.2008
93. U. Klinge: Two controversial concepts: Standard procedure in a standard patient versus tailored surgery with procedures adjusted to individual patients? 5. Suvretta-Workshop, St. Moritz: 1.-7.7.2008
94. U. Klinge: Degradationsprozesse und Netzbrüche in der Hernienchirurgie. 3. Wilhelmsburger Hernientage, Hamburg: 5.-6.9.2008
95. U. Klinge: Update Biomaterialien und Netze in der Hernienchirurgie. 12. chir. Forschungstage, Freiburg: 25.7.-29.9.2008
96. U. Klinge: Classification of incisional hernia - from Aachen‘s point of view. Consensus meeting on the development of an EHS classification, Gent, Belgium, October 2nd - 4th 2008
97. U. Klinge: What should be considered for selection of mesh material. AHS, Beijing, 1.-2.11.2008
98. U. Klinge: The CRPS after groin hernia repair. 4th International Congress of the Asia-Pacifric Hernia Society, 5th Annual Conference of China hernia Society, 30.10.-2.11.2008, Beijing
99. U. Klinge: Hernia repair tailored to the patient instead of using a gold standard?. 4th International Congress of the Asia-Pacifric Hernia Society, 5th Annual Conference of China hernia Society, 30.10.-2.11.2008, Beijing
100. U. Klinge: Future perspectives in textile implants. 4th International Congress of the Asia-Pacifric Hernia Society, 5th Annual Conference of China hernia Society, 30.10.-2.11.2008, Beijing
101. U. Klinge: Update mesh. Master class Shanghai. 28.11.2008
102. U. Klinge: Hernia and Collagen. 4. Rotterdam interactive congress for hernia, 21.11.2008, Rotterdam, NL

103. U. Klinge: Was ist bei der Auswahl von Meshes zu beachten? Zürser Hernienforum 14.12.-16.12.2008, Zürs, Austria
104. U. Klinge: Die „männliche Schlinge“ zur Therapie der Harninkontinenz. AGKAMED „Neue Behandlungswege der männlichen Inkontinenz“, Berlin, 12.5.2009
105. U. Klinge: Was bedeutet Biokompatibilität in der Chirurgie. 1.5.2009 München, Jahreskongreß der DGFC
106. U Klinge: Lightweight mesh Konzept. 28.4.2009 München, Jahreskongreß der DGFC
107. U Klinge: Welche Netze für die offene/laparoskopische Narbenhernienreparation ?. 30.4.2009 München, Jahreskongreß der DGFC
108. U. Klinge: Biomechanische Anforderungen:Was sollen und können Netze leisten ? 30.1.2009, Berlin 3-Chirurgen
109. U. Klinge: What has to be considered for selection of alloplastic nets and slings at the pelvic floor? 28.3.2009, Dijon
110. U. Klinge: Leuven Aachen Rotterdam Herniosis Studygroup LARHS 10.4.2009, Leuven
111. U. Klinge. Biologicals für die Hernienchirurgie? Jahreskongreß der Deutschen Herniengesellschaft in Neuss, 19-20.6.2009
112. U. Klinge. Mesh – structure or confusion? 4. Interrnationaler Welthernienkongreß in Berlin 9.-12.9.2009
113. U. Klinge: Das ideale Mesh? Euregio Bodensee, 3.7.2009 St. Gallen
114. U.Klinge: Limitation and peerspective of Biologicals. Leeds, 23.10.2009
115. U.Klinge: Update Narbenhernienchirurgie unter Einbeziehung von Grundlagen der Netzstabilität. Chirurgische Abteilung, Uniklinik Essen, 26.10.2009
116. U. Klinge: Principles of hernia repair. Masterclass Baden-Baden, 20.11.2009
117. U. Klinge: Biologicals. Masterclass Baden-Baden, 21.11.2009
118. U. Klinge: Update Literature for hernia. Masterclass Baden-Baden, 20.11.2009
119. U. Klinge: Textile structures fort he pelvic floor. Kopenhagen, 27.11.2009
120. U. Klinge: Biologicals as standard for hernia repair. 4. Berliner Hernien-Tage, 28.1.2010
121. U. Klinge: Das ideale Mesh: 4. Berliner Hernien-Tage, 30.1.2010
122. U. Klinge: Große Datenmengen für die Medizin? Arbeitstreffen E-Health, RWTH-Aachen, 25.1.2010
123. U. Klinge: Was unterscheidet die Netze ? DGfC Berlin 2010
124. U. Klinge: the ideal mesh. Oslo 4/2010
125. U. Klinge: What is the ideal mesh? Dubai 4/2010
126. U. Klinge: biologicals for every henria? Dubai 2010
127. U. Klinge: mesh classification? Dubai 2010
128. U. Klinge: Meshes für die Chirurgie. Fulda, EKK 17.5.2010
129. U. Klinge: Hernie - Gibt es eine einfache „Pathophysiologie“ München 11.6.2010 Deutsche Henriengesellschaft
130. U.Klinge: Wie kann man Meshes klassifizieren? BvMed 2.7.2010
131. U. Klinge: Gibt es eine einfache Pathophysiologie, DHG München, 10-12.6.2010
132. U. Klinge: Mesh in der Leistenhernienchirurgie. Schwarzenberg, Scheyer, Austria 1.-3.7.2010
133. U. Klinge: Basic principles of mesh implants and actual status of knowledge. Liedl, München Bogenhausen, 13-14.10.2010
134. U. Klinge: Alloplastische Materialien in der Hernienchirurgie – was gibt es Neues? Wilhelmsburger Hernientage 23-24.10.2010
135. U. Klinge: Biomechanics, immunology and tissue response to the mesh. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro

136. U. Klinge: Biologicaals. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
137. U. Klinge: Sublay, Why and How ? Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
138. U. Klinge: Paracolostomic hernia. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
139. U. Klinge: PVDF. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
140. U. Klinge. Prophylaxe der Hernienentstehung? Berliner Hernientage 24-29.1.2011
141. U. Klinge: Grundlagen und Materialien. Berliner Hernientage 24-29.1.2011
142. U. Klinge: Classification of surgical meshes for hernia repair. EHS, Gent, 11-13.5.2011
143. U. Klinge: Risk factors for incisional hernia development. EHS, Gent, 11-13.5.2011
144. U. Klinge: Statistics and analysis for biological material in hernia treatments – the current status quo. Cook Symposium. Berlin, 19-20.5.2011
145. U. Klinge: Biologische Netze heute. 1. Düsseldorfer Herniensymposium. 2.4.2011
146. U. Klinge: Chaos bei den Kunststoffnetzen: Vorschlag zur standardisierten Einteilung. DHG Oldenburg, 26-28.5.2011
147. U. Klinge: Das ideale Mesh. Fürth, 30.6.2011
148. U. Klinge: Surface modification: do we really need it ? EHS Winter conference, Madonna di Castillo, 10-12.3.2011
149. U. Klinge: Abdominal wall hernia, current update. 10. – 12.11.2012 Masterclass Baden-Baden
150. U. Klinge: Prophylaxe der Hernienentstehung. Symposium Rotkreuzklinikum München. 25.11.2012
151. U. Klinge: "Surface modification to direct tissue response" RICH, Rotterdam, 13.1.2012
152. U. Klinge: Grundlagen und Materialien. Hernia Kompakt, Hamburg, 19.1.2012
153. U. Klinge: Klassifikation von Netzimplantaten in der Hernienchirurgie. 4. Wilhelmsburger Hamburg, 20.1.2012
154. U. Klinge: Evidence based medicine - Was sollen wir glauben? 25.4.2012, DGfC, Berlin
155. U. Klinge: Uni Essen Chirurgie-Fortbildung: Hernienchrirugie – wann welches Netz. 21.5.2012
156. U. Klinge: Classification of meshes for risk assessment. EuraHS, Brüssel, 7.6.2012
157. U. Klinge: Change in pore size and weight of abdominal wall meshes: What did it bring us so far? Brüssel, 25.10.2012
158. U. Klinge: Materialien in der Hernienchirurgie. Hernia Kompact München, 24-26.10.2012
159. U. Klinge: EBM – was sollen wir glauben. Hernie interaktiv, München, 27.10.2012
160. U. Klinge: From view of experimental surgeon – meshes for pelvic floor. Munic, 17.11.2012
161. U. Klinge: Biomechanic aspects of meshes for pelvic floor surgery. Expert class Cologne Prof. Jäger, 7.-8.12.2012
162. U. Klinge Klassifikation der Netze. 25.-26..1.2013, 6. Berliner Hernientage
163. U. Klinge Sichtbare Netze, erste Ergebnisse, 25.-26.1.2013, 6. Berliner Hernientage.
164. U. Klinge Netz- und Materialentwicklung: Biomaterialien in der Chirurgie: Fluch oder Segen ? 59. Kongress der Nordrhein-Westfälischen Gesellschaft für Urologie. 11. – 12. April 2013 |Rheinterrasse Düsseldorf.
165. U. Klinge: Individual patient centred outcome research as alternative to randomized controlled trials (RCT). Gdansk EHS 14.5.2013, EHS

166. U. Klinge: Ist Randomisierung der Schlüssel zur evidenzbasierten Hernienchirurgie ? Cottbus 7.-8.6.2013, DHG
167. U. Klinge Das richtige Netz TAPP / TEP / offen. Saale-Unstrut, 29.6.2013
168. U. Klinge. Textile meshes in Surgery: FDA Warnings – New Standards – Registries - What can we learn from Hernia Surgery? Barcelona ICS. 29.8.2013
169. U. Klinge Moderne Netz-Technologie. 2. Düsseldorfer Hernien-Symposium Zarras, 26.9.2013

Grants

	Principal investigator, co-workers	**topic**	**Supporter, duration**	**period**	**Amount of resources**
	Klinge, Höer	Panacryl-Fadenstudie	Ethicon / 3 Jahre	1999-2002	260.000
	Klinge, Welty	Internationale Vypro-Studie	Ethicon / 3 Jahre	1999-2002	54.000
	Klinge, Welty	SHM-Studie	Ethicon / 2 Jahre	1997-1999	262.000
	Klinge	Kollagen-Studie	Ethicon / ½ Jahr	1999	30.000
TV 9	Klinge	Verwendung von Biomaterialien beim Bauchdeckenverschluß	BIOMAT 4 Jahre	1995-1998	208.107
TV 41/42	Klinge/Steinau	PVDF-Mesh	BIOMAT 2 Jahre Nachfolgeprojekt 2 Jahre	1999-2000 2001-2002	347.940
	Klinge	Mesh-Entwicklung	Ethicon	2000-2003	375.000 Kostenstelle: 9876170 Anforderungsnr.: 98761770
TV 66	Mertens, Klinge	Mesh-Fibroblasten	BIOMAT	2001-2002	330.000
TV 61	Bertram, Tietze, Klinge	Kokulturen	BIOMAT	2001-2002	210.000
FEG/BMBF	Klinge, Klosterhalfen	Entwicklung von neuartigen bioverträglichen Netzmaterialien zur anatomisch angepaßten chirurgischen Hernientherapie - Beschichtete Meshes	03N4024 FEG-065/1-2001	1.3-2001-2004	358.824,-
DFG	Klinge, Klosterhalfen, Mertens	Kollagen und Hernie	KL 1320/2-1	21.6.2001-21.6.2003	350.000,-
Ethicon	Schumpelick,	Optimierung von Mesh-Strukturen	370253	1.4.2003-	360.000 €

	Principal investigator, co-workers	**topic**	**Supporter, duration**	**period**	**Amount of resources**
	Klinge, Stumpf, Junge, Schachtrupp, Steinau, Schwab			31.3.2006	
DFG	Lynen-Jansen Mertens Klinge Jansen	Einfluß von Biomaterialien auf die MMP-2 Genexpression in vivo	DFG JA1123/1-1	2004-2005	120.000 Euro
DFG-Projekt	Lynen-Jansen Mertens Klinge Jansen ,	Untersuchungen zur Gewebe-Integration von Biomaterialien bei selektiver Blockade der TNFα-abhängigen MMP-2 Expression'	DFG JA 1123/1-2,	Laufzeit 2 Jahre, Umfang Start 2008	ca. 120.000 Euro,
INNONET	HIA und Frauenhofer	Die sichere Naht	VDI/VDE	2/2008-2011	Gesamtvolumen 1,1 Mill €
Mesh insight	FEG und UK-Aachen Klinge U, Otto J, Krämer N, Obolenski B:	Sichtbarmachung von textilen Implantaten im MRT durch Einlagerung von superparamagnetischen Eisenoxid-Nanopartikeln. Innovationswettbewerb 2007 des BmbF zur Förderung der Medizintechnik, 18.10.2007	BMBF 01EZ0849	1.4.2008-31.1.2011. 3.2008-1.2.2011	Gesamtvolumen ca. 900.000€
	Kämmer, Otto, Klinge	PVDF-Mesh Beschichtung mit NN-Hormonen	ESAC	2008	12 000€
Bioinside	FEG/Fiebeler/Berlin	Beschichtung mit DHEA	BMBF BioInside 13N9827-13N9833 PN 372552	2008-2010	70 000€
	Klinge	InnoMeT.NRW: Patientenadaptierte Medizintechnische Lösungen für die Kardiovaskuläre Therapie	005-1003-0067 IAN 700584	1.8.2010-31.7.2013	270 000
	Klinge	Elastisches Netz-Implantat für die Chirurgie am Zwerchfell (Hiatus-Mesh)	ZIM-Projekt KF2621701AJ0	14.4.2010-31.10.2011	110 000€
	Klinge/Tolba	Covidien Stapler Pase I	372708	1.2.2010-31.1.2011	120 000 Eur
	Klinge/Tolba	Covidien Stapler Pase II	372708	1.4.2011-31.3.2012	180 000 Eur
	Klinge et al, ZIM 3D	3D Implantat	ZIM / AiF 13EZ1201C	1.10.11-30.9.2013	174 893 €
	Klinge et al. ZIM Hiatus-Mesh	Zwerchfell-Netzimplantat	ZIM / AiF KF2621701AJ0	1.4.10-31.11.2011	110 365 €
	Klinge et al E-	Elastisches Mesh	01EZ1201C	1.6.2012-	240 000€

	Principal investigator, co-workers	**topic**	**Supporter, duration**	**period**	**Amount of resources**
	Mesh BMBF (DLR)			31.5.2015	

Patents:

02754251.3-2107-DE0202287 FEG Textiltechnik vom 25.6.02: Textiles Implantat mit monofilen Polyvinylidenfluorid-Fäden

„Einstückiges Stomaunterstützungsimplantat“ WO 2008/031411 A1

„Medizinisches Implantat mit Oberflächenbeschichtung“ AZ 10 2009 005 792.7

„Meshförmiges Implantat“ (Mesh mit Ferrofluiden) PCT/DE 2008/000805

„Textiles Intraperitoneal-Mesh“ DE 10353930.1

„Textiles Erzeugnis mit Oberflächenmodifikation und entsprechendes Verfahren zur Oberflächenmodifikation“ PCT/DE02/04291

„Textiles Implantat“ WO PCT/DE02/02287

EXHIBIT

B

Date	Bates Number	Title	Deposition Exhibit
November 2010-October 2011	ETH.MESH.00562421	Untitled PPT update	
3/26/2008	ETH.MESH.02170708	Email from David Robinson to Dr. Vincent Lucente re: UP	
	ETH.MESH.01760854	David Robinson, Gynemesh PS Clinical Expert Report	
8/14/2007	ETH.MESH.00869908	Thunder Meeting Minutes	
7/31/2007	ETH.MESH.01819505	Thunder Meeting Minutes	
	ETH.MESH.01405166	"Exploratory Program 'Thunder' A Material designed for Pelvic Floor" Powerpoint presentation By: Clifford Volpe and Peter Meier	
4/12/2007	ETH.MESH.00832555	Thunder Meeting Minutes	Batke T-1248
	ETH.MESH.00742724	"Ethicon Women's Heath & Urology: Project Lightning Update"	
2/13/2006	ETH.MESH.00585937	Email from Gene Kammerer to Quentin Manley et al re: TVM Discussions	
2/26/2004	ETH.MESH.02270823	Email from Joshua Samon to Scott Ciarroca et al. re: mesh implants - user needs	
1/18/2005	ETH-18761	Email from Kelly Brown to Gene Kammerer re: Proposal for work with CBAT	
3/25/2004	ETH.MESH.01988643	Email from Vincenza Zaddem to Scott Ciarrocca re: disclosure questions	
	ETH.MESH.01424246	Holste, J; Test report No.: B0086/02, Histopathological report/Immunohistochemical report	
2001	ETH.MESH.02017169	Hellhammer, B., *Meshes in Pelvic Floor Repair – Findings from literature review and interviews with surgeons.*	Hellhammer T-4002
	ETH.MESH.03719177	Chris Vailhe report “Polypropylene Mesh for Pelvic Floor Repair (PFR) – Focus on Mesh Exposure – Road to Improvement	

06/2009	ETH.MESH.02157879	Klosterhalfen B., *Interim Report Mesh Explants Pelvic Floor Repair*	Burkley T-0280 Holste T-1211
	ETH.MESH.01819528	WW Customer Complaints – received from Carey Brennan	
1/13/2005	ETH.MESH.02286052	Email from Sean O'Bryan to Scott Ciarrocca re: IFU Prolift	
03/2009	ETH.MESH.00017369	Elmer C, Blomgren B, Falconer C, Zhang A, and Altman D; *Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery.* The Journal of Urology Vol. 181, 1189-1195, March 2009	
01/2009	ETH.MESH.00017239	Elmer C., Altman D., Ellstom Engh M., Axelsen S., Vayryen T., and Falconer C.; *Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse.* ACOG Vol. 113, No. 1, January 2009	
2/1/2006	ETH.MESH.0394544	Memo to Sunny Rha re: Global Regulatory Strategy - Gynecare TVT - Laser Cutting Project	
11/21/2005	ETH.MESH.00301741	Email From Dan Lamont to Jacqueline Flatow re: !!!!!GREAT NEWS FOR TVT LASER CUT MESH!!!!!	Barbolt T-2119
10/12/2005	ETH.MESH.0353750	Letter from Carol Holloway to Herve Fournier re: TVT Device, Blue Mesh	
	ETH.MESH.02059212	Prolift Surgical Guide	
	ETH.MESH.01221055	Pariente J-L; *An independent biomechanical evaluation of commercially available suburethral slings.* Issues in Women's Health	Barbolt T-2121
6/6/2000	ETH.MESH.03904451	Meshes in Pelvic Floor Repair	
11/22/2006	ETH.MESH.02992137	Lightning Clinical Strategy	
4/5/2007	ETH.MESH.01218361	"State of the knowledge in 'mesh shrinkage' - What do know" by Kerstin Spychaj	
3/4/2008	ETH.MESH.00832562	Thunder Meeting Minutes	
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2010	ETH.MESH.01192895	Velemir L, Amblard J, Fatton B, Savary D, Jacquetin B, *Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study.* Ultrasound Obstet Gynecol (2010)	
6/22/2011	ETH.MESH.07192929	PA Consulting report "Investigating Mesh Erosion in Pelvic Floor Repair"	Vailhe T-1116
2/27/2008	ETH.MESH.03731339	Email from Dan Smith to Matter Henderson, et al. re: tape position at rest	
2/28/2005	ETH-03558	DDSA	
2/17/2011	ETH.MESH.01264497	Email from Vincenza Zaddem to Vernon Ghee et al. re: Mesh pore size - tissue compliance and contraction	
1/17/2010	ETH.MESH.01785259	Email from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation	
4/22/2009	ETH.MESH.02148431	Email from Dr. Joerg Holste to Jonathan Meet, et al. re: Question on Monocryl absorption	Holste T-1199
11/18/2008	ETH.MESH.00008072	Ethicon PFR online training course	
8/23/2007	ETH.MESH.00000272	Email from Vincenza Zaddem to David Robinson re: macroporous - lower limit of pore size	
3/28/2007	ETH.MESH.00593165	Vailhe Technical report	
	ETH.MESH.00237968	"R&D Perspective - The Journey from Prolift to Prolift +M" Powerpoint by Cliff Volpe	
2007	ETH.MESH.01782867	"Factors Related to Mesh Shrinkage" by Kerstin Spychaj	
2/23/2007	ETH.MESH.02017152	Expert Meeting Minutes	
6/2/2006	ETH.MESH.00870466	Expert Meeting Minutes	
6/14/2006	ETH-83454	Email from Scott Ciarrocca to Rebecca Leibowitz, et al. re: Mesh Microns	
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2005	ETH.MESH.02232937	Klosterhalfen, B., K. Junge, and U. Klinge, *The lightweight and large porous mesh concept for hernia repair* .	
2004	ETH.MESH.00280338	Berrocal J., Clave H., Cosson M., Debodinance Ph., Garbin O., Jacquetin B., Rosenthal C., Salet-Lizee D., Villet R., *Conceptual advances in the surgical management of genital prolapse The TVM Technique;*	
10/14/2003	ETH.MESH.01220710	Email from Gene Kammerer to Georgina NG re: Technical data on competitve meshes from Europe	
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1/16/2001	ETH.MESH.01160507	Email from Edward Dormier including the December 2000 Corporate Product Characterization	
	ETH.MESH.01992236	"Form for Test Method Applicability/Suitability"	
1/18/2008	ETH.MESH.00906445	Email from Vincenza Zaddem to Bryan Lisa re: 510(k) mesh data with strength	
	ETH-01754	FDA letter stating necessary force for arm pull-out	
12/15/2008	ETH.MESH.00067363	Email attaching Vincent Lucente Webinar Transcript	
	ETH.MESH.02227368	Meshes/Devices Chart	Holste T-1192
	ETH.MESH.02212840		
	ETH.MESH.00081180	Prolift Characteristics	

9/10/2007	ETH.MESH.021989933	Email From Christoph Walther to Vincenza Zaddem re: "Info needed for FDA"	Hellhammer T-3240
8/29/2007	ETH.MESH.00080842	Letter from Dr. Jiyoung Dang to Bryan Lisa regarding Prolift & Prolift +M changes	
9/12/2007	ETH.MESH.00922443	Email from Vincenza Zaddem to Price St. Hilaire et al. regarding bidirectional elasticity statement	Hellhammer T-3241
6/18/2007	ETH.MESH.01405170	"Exploratory Program 'Thunder'" Powerpoint presentation By: Clifford Volpe and Peter Meier	
5/9/2008	ETH.MESH.02227224	"MGPP Thunder Decision Meeting" powerpoint presentation	
12/1/2006	ETH.MESH.02195798	Email from Axel Arnuad re Strength	
6/26/2008	ETH.MESH.02195788	Prolift +M DRM	
3/7/2007	ETH.MESH.00078537	Email from Joerg Holste re: Lightning 510(k) requirements	
10/26/2008	ETH.MESH.02207388	Email from Jonathan Meek to Julie Bird et al. re: Prolift +M Pre-Reading	
2012	ETH.MESH.03753245	"Biomechanics (Pelvic Forces) PowerPoint	
	ETH.MESH.00396836	"Review of Surgical Techniques using Mesh" by David Robinson	
5/8/2008	ETH.MESH.00318775	Email from Mark Yale to Jennifer Paine, Jonathan Meek et al. re: Prolift mesh was "not specifically design".	
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2009	ETH.MESH.01264260	Piet Hinoul Presentation	
2004	ETH-65881	Gynecare Prolift IFU	
2003	ETH.MESH.02053630	Gynemesh PS "White Paper"	
1/23/2003	ETH-03883	"Prolene Resin Manufacturing Specifications" by John Karl	
2/28/2005	ETH-03534	DDSA Appendix II Prolift "Summary Report"	
2/28/2002	ETH-03558	DDSA Appendix VI "Form" describing hazards	
7/20/2007	ETH.MESH.05920616	Email from Martin Chomiak to Boris Batke, et al. re Defining light weight mesh	Batke T-1227 Batke T-1229 Burkley T-0288
	ETH.MESH.01816990	Kammerer Product development chart	Holste T-1193/T-1194
	ETH.MESH.05479535	Microporous, Medium & Macroporous grid	Batke T-1230
3/13/2006	ETH.MESH.05446127	Email from Holste to Engel et al. re: Mesh and tissue contaction in animals	Batke T-1231
03/2011	ETH.MESH.05479718	"Ethicon Polypropylene Mesh Technology" Powerpoint by Boris Batke	Batke T-1233
4/17/2003	ETH.MESH.05920530	Email from Boris Batke to Jill Schiaparelli et al. re Literature list of Lightweight Meshes	Batke T-1234
2/2/2008	ETH.MESH.05920618	Email from Petra Koehler to Boris Batke, et al. re Dr. Schumpelick	Batke T-1235
3/1/2012	ETH.MESH.04015102	Email from Boris Batke to Casey Mayes re AWES Pelvic Floor Conference - Gala Dinner invitation	Batke T-1236
6/3/2012	ETH.MESH.05585066	"Ultrapro" PowerPoint presentation by Boris Batke	Batke T-1237

	ETH.MESH.05916450	"Chronic Pain Prevention/future - Bioengineer's point of view"	Batke T-1238
	ETH.MESH.04037600	"Innovations in Mesh Development" By Boris Batke	Batke T-1239
	ETH.MESH.05479410	"The (clinical) argument of lightweight mesh in abdominal surgery" presentation by Boris Batke	Batke T-1240
5/4/2004	ETH.MESH.05918776	Email from Jill Schiaparelli to Karen Zaderej, Boris Batke et al. re Marlex experience	Batke T-1241
1/13/2005	ETH.MESH.04036976	Dynamesh, Dynamesh Light, Dynamesh IPOM: Analysis of Competitor meshes: Report	Batke T-1247
		Material Specification for TVT Prolene	Batke T-1249
	ETH.MESH.02219202	Polypropylene Mesh Roll Stock	Holste T-1196
4/3/2009	ETH.MESH.02184435	Email from Osman Rathore to Meng Deng et al. re Analytical characterization - Optimization of Structure	Burkley T-0269
3/1/2012	ETH.MESH.07226377	Email from Laura Vellucci to Dennis Jamiolkowski re Polypropylene mesh	Burkley T-0272
2/29/2012	ETH.MESH.04038180	Email from Dennis Jamiolkowski to Laura Vellucci et al. re Your Professional Opinion	Burkley T-0273
3/5/2012	ETH.MESH.04937874	Email from Piet Hinoul to Laura Vellecci et al. re Polypropylene mesh	Burkley T-0274
3/6/2012	ETH.MESH.07212397	Response to email from Clare Huntington 26 Jnauary 2012 (15:38) with attached publication: "*Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*" , *Int Urogynecol J (2010) 21:261-270*	Burkley T-0275
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3/7/2012	ETH.MESH.07226404	Email from Dennis Jamiolkowski to Laura Vellucci et al. re Information on PROLENE Suture and PROLENE Mesh	Burkley T-0278
		Klosterhalfen B., Interim Report Mesh Explants	Burkley T-0279
04/2008	ETH.MESH.00006636	Pelvic Floor Repair	Holste T-1210
	ETH.MESH.07726805	Burkley notes on Dr. Klinge Prolift expert report	Burkley T-0281
10/15/1992	ETH.MESH.05453719	Seven Year Data for Ten Year Prolene Study: ERF 85-219	Burkley T-0282
12/14/2010	ETH.MESH.02588977	ERM team Meeting Minutes	Burkley T-0283
	ETH.MESH.03699547	PA Consulting Cost	Burkley T-0284
		PA Consulting "Investigating Mesh Erosion in Pelvic	Burkley T-0285
5/18/2011	ETH.MESH.02589032	Floor Repair" Draft	Vailhe T-1114
3/31/2011	ETH.MESH.07198250	Email Christophe Vailhe to Joe Robinson re: Thanks & pictures	Burkley T-0286
7/3/2002	ETH.MESH.02183537	Porosity Measurements of Various Meshes by D.F. Burkley	Burkley T-0289
2/17/2010	ETH.MESH.05443495	Porosity Measurements of Various Meshes by D.F. Burkley	Burkley T-0290
	ETH.MESH.05443059	Operating Procedure for Optical Evaluation to Determine Porosity of Mesh Samples Using the Nikon Stereomicroscope and Image-Pro Image Analysis System	Burkley T-0291
	ETH.MESH.05443077	AST-2010-0587 "Pore Size Measurement of Surgical Mesh Products"	Burkley T-0292
1/2/2006	ETH.MESH.00585906	Email from Gene Kammerer to Sunny Rha re TVT - TVT-O Specifications	Burkley T-0293
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	ETH.MESH.05918082	"Solving the Device Design Puzzle" Powerpoint	Burkley T-0299
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4/7/2004	ETH.MESH.07190442	Memo to Josh Samon from Michael Pelekis re Risk Assessment for Laser Cutting of D'art Gynemesh PS Implants	Burkley T-0301
8/26/2011	ETH.MESH.06261965	Email from John Karl to Bob Washington et al. re: Braskem…..A Little History	Burkley T-0303
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4/27/2005	ETH.MESH.03908707	Email from Paula Evans to Gynecare Marketing & Gynecare Umbrella re PROLENE vs. polypropylene	Burkley T-0306
3/9/2006	ETH.MESH.00750766	Interim Report, PSE Accession NO: 05-0070 "Test and Control Article Material Characterization Program" with TVT-Secur Implant and EO Sterilization	Burkley T-0308
4/27/2010	ETH.MESH.02185004	Email from James Flint to Elizabeth Vailhe re surface area	Burkley T-0309
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2/16/2011	ETH.MESH.03146492	Email from Joerg Holste to Judi Gauld et al. re Prosima +M clin stra	Holste T-1198

3/13/2006	ETH.MESH.05446127	Email from Joerg Holste to Dieter Engel re Mesh and Tissue Contraction in Animal	Holste T-1202
	ETH.MESH.00838428	"Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery" powerpoint presentation By A. Arnaud & D. Robinson	Holste T-1203
10/2/2003	ETH.MESH.05483362	"ULTRAPRO Mesh Pricing Committee Presentation"	Holste T-1204
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11/2004	ETH.MESH.00659678	The TVM Group, "Conceptual advances in the surgical management of genital prolapse" article	Holste T-1206
	ETH.MESH.05718952	Project Edelweiss Characteristics grid	Holste T-1207
3/11/2005	ETH.MESH.05549189	Email from Joerg Holste to Sandy Savidge re Infection Risk implantation TVT-U	Holste T-1208
	ETH.MESH.05505944	Clinical Infection Risk Assessment for Gynecare TVT Universal (TVT U)	Holste T-1209
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6/2/2005	ETH.MESH.06403725	Final Report: Ethicon Study No. SOD4/2-2-1: A 3 month pre-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model	Holste T-1217
1/3/2006	ETH.MESH.05246116	Email from Dan Smith to Allison London Brown et al. re Results of TVTx preclinical trial	Holste T-1218
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2/28/2006	ETH.MESH.04939027	Corporate Prodcut Characterization Plan for Gynecare TVT S (Secur)	Holste T-1220
11/28/2005	ETH.MESH.00019925	Letter to Patrica Hojnoski from FDA re Gynecare TVT Secure System	Holste T-1221
7/16/2010	ETH.MESH.04940233	Preclinical Efficacy Assessment for ETHICON GYNECARE GYNEMESH M	Holste T-1224
1/20/2010	ETH.MESH.05127423	Email from Joerg Holste to Petra Koehler and Axel Arnaud re Tissue reaction ULTRAPRO	Holste T-1225

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2/1/2012	ETH.MESH.07200381	Email from Christophe Vailhe to Clifford Volpe Re Exposure Position Norderstedt 2012.pptx	Vailhe T-1109
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2/17/2011	ETH.MESH.07192242	Email from Peter Meier to Julie Bird et al., Re Sales reps in UK	Vailhe T-1113
7/21/2011	ETH.MESH.07198825	Email from Christophe Vailhe to Ian Rhodes at PA Consulting re Mesh erosion report attached	Vailhe T-1115
1/20/2011	ETH.MESH.07192012	PA Consulting Group - Mesh Erosion Interview - Surgeon (Rhona Kearney)	Vailhe T-1117
1/18/2011	ETH.MESH.07192412	PA Consulting Group - Mesh Erosion Interview - Pathology (Klosterhalfen)	Vailhe T-1118
1/14/2005	ETH-07152	Clinical Expert Report: GYNECARE PROLIFT Pelvic Floor Repair System by Charlotte Owens	Vailhe T-1119
2/9/2011	ETH.MESH.07197998	Email from Christophe Vailhe to Michael Richter et al. Re: You have been selected - Forces on the pelvic floor - challenge to determine	Vailhe T-1120
5/18/2011	ETH.MESH.07192872	Email from Piet Hinoul to Pann Hermansson and Christophe Vailhe Re Forces in the pelvic floor	Vailhe T-1121
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	ETH.MESH.07876572	TVT Secure 510(k)	Barbolt T-60

	ETH.MESH.01217925	An exploratory 91-Day Tissue Reaction Study of Polypropylene Based Surgical Mesh in Parts (PSE ACC. NO. 00-0035)	P-1150
8/8/2006	ETH.MESH.02091873	Holste & Barbolt signed ISO 10993 testing documents	Barbolt T-2112
2/27/2004	ETH.MESH.00863391	Email from Dan Smith to Janice Burns re Important: 2 TVT complaints concerning allegedly brittle mesh	Barbolt T-2115
11/10/2004	ETH.MESH.02180828	Letter from Dr. Eberhard	Barbolt T-2116
10/18/2004	ETH.MESH.02180833	Translation of Dr. Eberhard letter	Barbolt T-2117
10/12/2005	ETH.MESH.03535750	Letter to Herve Fournier RE 810041B TVT Device, Blue Mesh - complaint	Barbolt T-2118
2/15/2006	ETH.MESH.00584291	Email from Jacqueline Flatow to Sungyoon Rha et al. Re Dver protocol for particle loss	Barbolt T-2120
5/1/2006	ETH.MESH.03358217	Email from Gene Kammerer to Herve Fourier re French Standard on TVT & Meshes	Barbolt T-2122
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5/9/2006	ETH.MESH.01219629	Email from Jacqueline Flatow to Gene Kammerer re Particle loss on TVT	Barbolt T-2124
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8/31/2007	ETH.MESH.00844331	Email from David Robinson to Yukie Yamano et al. Re: Asking TVT Complication? - Fraying	Barbolt T-2126
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6/18/1999	ETH.MESH.05315240	A 28-Day Intramuscular Tissue Reaction Study in Rats of Polyropylene Mesh from the TVT (Ulmsten) Device (PSE ACCESSION NO. 97-0197)	Barbolt T-2128
7/19/1996	ETH.MESH.04447134	Corporate Product Characterization - Product Safety Profile (Prolene)	Barbolt T-2129
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10/1/1997	ETH.MESH.08218337	Literature Review on Biocompatibility of Prolene Sutures and Implants	Barbolt T-2131
	ETH.MESH.02134271	Mechanisms of Cytotoxicity for TVT Polypropylene Mesh (DRAFT)	Barbolt T-2132
3/5/2003	ETH.MESH.05316755	Histological Evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in A Rabbit Model	Barbolt T-2133
8/8/2005	ETH.MESH.07876890	Examination of an Extract of TVT-Secur Implant ETO Steril, Implantat for Cytotoxix Properties in a Cell Culture Test	Barbolt T-2134
8/8/2005	ETH.MESH.07876905	Intracutaneous Test of an Extract of TVT Secur Implant ETO Steril Implantat in Rabbits	Barbolt T-2135
8/8/2005	ETH.MESH.07876870	Examination of an Eluate of TVT-Secur Implant ETO Steil, Implanat of Pyrogenic Properties in Rabbits	Barbolt T-2136
	ETH.MESH.07876820	K052401: Response to FDA's Request for Additional Information: Gynecare TVT Secur System	Barbolt T-2137
1/28/1998	ETH.MESH.00371496	Letter to Gregory Jones from FDA re Tension Free Vaginal Tape (TVT) System	Barbolt T-2105
11/2/2001	ETH.MESH.07469275	Biocompatibility Risk Assessment for TVT-AA - Revised	Barbolt T-2106
12/8/2003	ETH.MESH.00019863	TVT-O 510(k)	Barbolt T-2107
2/8/2006	ETH.MESH.00874032	Email from Mark Yale to Cindy Crosby et al. Re: MHRA Request - TVT (change to dying process)	Barbolt T-2108
6/6/2001	ETH.MESH.01159961	Biocompatibility Risk Assessment for the TVT-L Device	Barbolt T-2109
8/27/2008	ETH.MESH.06851860	Gynecare TVT AA - CE Mark Technical File	Barbolt T-2110
	ETH.MESH.02026591	Sunoco MSDS	Barbolt T-2111
7/9/1992	ETH.MESH.09557798	7 Year Dog Study with explant images	
3/30/2012	ETH.MESH.03949361	Dyed Prolene Batch Review	
10/1/1992	ETH.MESH.09557819	Handwritten notes from 7 year dog study	
	ETH.MESH.00339437	5 years Sales Piece - TVT	

	ETH.MESH.09671620	Weights, elasticity etc chart	
	ETH.MESH.09651393	Invention disclosure	Trzewik T-3249
	ETH.MESH.09654601	Uniaxial Test- theoretical considerations	
	ETH.MESH.03032928	FDA Review - R&D	Hellhammer T-4018
	ETH.MESH.02995494	"Evidence to Support Innovation" PowerPoint presentation by Judi Gauld	
12/21/2007	ETH.MESH.02588170	Slide from Trzewik presentation	
6/6/2000	ETH.MESH.03924557	"Meshes in Pelvic Floor Repair" By Brigitte Hellhammer	
	ETH.MESH.03658980	TVT-PA 510 (k)	
7/9/2007	ETH.MESH.05588123	Email from Stephen Wolhert to Brigitte Hellhammer et al. re Costello Article	Hellhammer T-4012
2008-2010	ETH.MESH.02340504	Gynecare TVT IFU	
2006	ETH.MESH.00584491	Email re AFNOR standards	
2010-Present	ETH.MESH.03427878	TVT IFU	
2006-2008	ETH.MESH.05222673	TVT IFU	
2005-2006	ETH.MESH.02340471	TVT IFU	
2003-2005	ETH.MESH.02340306	TVT IFU	
2001-	ETH.MESH.05225354	TVT IFU	
	ETH.MESH.02340568	TVT-S IFU	
	ETH.MESH.02340902	TVT-O IFU	
	ETH-10187	Prolift Patient Brochure	
	ETH.MESH.00748451	Prolif & Prolift +M 510	
	ETH.MESH.02341954	Prolift & Prolift +M Patient Brochure	
	ETH.MESH.00006796	Stand and Deliver PowerPoint Presentation	
	ETH.MESH.04941016	Lightweight Mesh Development PowerPoint by Juergen Trzewik	
7/6/2007	ETH.MESH.05447475	Email from Dieter Engel to John Gillespie et al. re How inert is polypropylene?	
	ETH.MESH.05237872	"Mesh Properties - How Important are they?" by Peter Meier	
1999	ETH.MESH.05644163	Pelvic Floor Repair – Surgeon's Feedback on Mesh Concept	

8/4/2009	ETH.MESH.04066979	Email re Dynamesh in Brazil	
6/23/1998	ETH.MESH.09266657	Email from Larry Ellington re Prolene Mesh for TVT	
	ETH.MESH.05225380	TVT IFU	Smith T-2139
	ETH.MESH.02340331	TVT IFU	Smith T-2140
	ETH.MESH.03427878	TVT IFU	Smith T-2141
2007	ETH.MESH.06861473	Gynecare TVT Secure Competitive Product Update PowerPoint presentation	Smith T-2142
7/12/2000	ETH.MESH.01317515	Preventia document	Smith T-2143
8/21/2000	ETH.MESH.03909708	Email from Axel Arnaud re Pelvic Floor Repair Procedural Strategy	Smith T-2144
10/2000	ETH.MESH.04044797	TVT Update: Success & Complications (Causes and recommendations)	Smith T-2145
6/22/2001	ETH.MESH.02089392	Scientific Advisory Panel on Pelvic Floor Repair - Preliminary Minutes	Smith T-2146
4/25/2002	ETH.MESH.01317510	Device Design Safety Assessment (DDSA) Re-Evaluation for TVT	Smith T-2147
12/2/2005	ETH.MESH.04385229	Clinical Expert Report - Gynecare TVT Secur System	Smith T-2148
1/29/2009	ETH.MESH.04093125	Email from Meng Chen re TVT IFUs on tape extrusion, exposure and erosion	Smith T-2149
	ETH.MESH.04081189	Meeting agenda	Smith T-2150
12/17/2008	ETH.MESH.00772231	Email from Robin Osman re Updated Fair Balance for TVT Brochure	Smith T-2151
12/17/2008	ETH.MESH.00772228	Email from Robin Osman re 2008 Budget Spend	Smith T-2152
12/18/2008	ETH.MESH.00339083	Email from Bryan Lisa re TVT Patient Brochure Fair Balance/EPI changes	Smith T-2153
3/2/2004	ETH.MESH.00865322	Email from Charlotte Owens re Reminder on BLUE mesh!	Smith T-2154
3/9/2004	ETH.MESH.00863405	Email from Brian Luscombe re Complaint TVTO	Smith T-2155
	ETH.MESH.01805985	"The Mesh Story" PowerPoint presentation by Dan Smith	Smith T-2156

11/10/2009	ETH.MESH.06921060	Email from Joseph Lanza re Preread for Web Conference	Smith T-2157
	ETH.MESH.06696593	Design FMEA TVT LCM Project	Smith T-2160
	ETH.MESH.06856958	"Gynecare TVT Obturator System" PowerPoint Presentation	Smith T-0241
10/13/2002	ETH.MESH.03910183	Email from Axel Arnaud re Soft Prolene	T-0353
6/6/2001	ETH.MESH.03905472	Email from Martin Weisberg re TVT recommendation from Dr. Alex Wang	T-0365
2/27/2004	ETH.MESH.00863391	Email from Dan Smith re Important: 2 TVT Complaints concerning allegedly brittle mesh	T-0366
11/10/2004	ETH.MESH.02180828	Dr. Eberhard Compliant	T-0367
10/18/2004	ETH.MESH.02180833	Translation of Dr. Eberhard letter	T-0369
5/9/2006	ETH.MESH.00585802	Email from Gene Kammerer re Particle Loss on TVT	T-0371
6/12/2006	ETH.MESH.00585842	Email from Gene Kammerer re TVT LCM - particle loss (reimbursement submission)	T-0372
	ETH.MESH.03932912	The History of TVT	T-0406; T-0833
	ETH.MESH.06859904	"TVT: Insights into the Making of a Revolution" by Sheri Dodd	T-0408
11/7/2005	ETH.MESH.05220458	Email from Wanda Petire-Singer re TVT Records	T-0410
	ETH.MESH.03714599	Unsigned Clinical Expert Report Gynecare TVT Secur System	Smith T-0455
9/15/2005	ETH.MESH.03905619	Email from Martin Weisberg re clinical expert report	Smith T-0456
11/18/2003	ETH.MESH.00541379	"Mesh fraying for TVT Devices" memo	T-0531
10/21/2008	ETH.MESH.02310653	Email from Sandy Pompilio re Information about FDA notification on use of mesh in pelvic surgery	T-0723
12/10/2004	ETH.MESH.01811770	Email from Steve Bell re VOC on Laser Cut Mesh	T-0974
	ETH.MESH.06857406	"TVT-Bridge) Retaining Leadership" PPT	Smith T-2159 Smith T-2161
	ETH.MESH.01265223	Risk Managent Report (legacy) for TVT and TVT-O	Smith T-0416
	ETH.MESH.00070187	Company Procedure for Medical Device Risk Management Plan	Smith T-2162

11/29/2004	ETH.MESH.01811758	Email from Paul Parisi re TVT Laser Cut mesh business case (for meeting this afternoon)	Smith T-2163
1/18/2011	ETH.MESH.08474562	2010 Performance and Development Plan Summary for Daniel Smith	Smith T-2165
	ETH.MESH.01816988	Mesh Timeline	Smith T-2166
	ETH.MESH.00838428	"Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery" powerpoint presentation By A. Arnaud & D. Robinson	Smith T-2168
		Section of Ethicon Powerpoint showing Weights	Smith T-2169
04/2008	ETH.MESH.06867612	"Matrix Material" PowerPoint Presentation	Smith T-2170
2002	ETH.MESH.06894461	Klinge, U., Klosterhalfen, B., Birkenhauser, V., Junge, K., Conze, J., Schumpelick, V. *Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model* . Journal of Surgiccal Research. 103, 208-214 (2002)	Smith T-2171
	ETH.MESH.06893952	"Evaluation of UltraPro Meshes" PowerPoint Presentation	Smith T-2172
11/26/2002	ETH.MESH.03910418	Email from Axel Arnaud re Mini TVT - mesh adjustment	Smith T-2173
1/16/2007	ETH.MESH.06868377	Email from Reinhard Juraschek re shrinkage review	Smith T-2174
3/4/2008	ETH.MESH.08474542	2007 Performance and Development Plan Summary for Daniel Smith	Smith T-2175
2/28/2003	ETH.MESH.01222617	Histological Evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in A Rabbit Model	Smith T-2176
	ETH.MESH.06923868	TVTO-PA Clinical Strategy	Smith T-2177
1/20/2012	ETH.MESH.08474570	2011 Performance and Development Plan Summary for Daniel Smith	Smith T-2178
3/8/2009	ETH.MESH.08474547	2008 Performance and Development Plan Summary for Daniel Smith	Smith T-2179
1/25/2010	ETH.MESH.08474555	2009 Performance and Development Plan Summary for Daniel Smith	Smith T-2180

9/13/2010	ETH.MESH.06917699	Form for Customer Requirements Specification (CRS) For Project TVT-O PA	Smith T-2181
08/2010	ETH.MESH.02218268	"TOPA & SCION PA Alignment" PowerPoint Presentation	Smith T-2182
11/1/2004	ETH.MESH.05548122	Email from Dan Smith re Update from the Oct 27 cadaver	Smith T-2183
12/14/2004	ETH.MESH.01809080	Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	Smith T-2184
6/18/2008	ETH.MESH.04048515	Meeting minutes re Project Scion	Smith T-2185
	ETH.MESH.01228079	Nilsson Podcast Transcript	Smith T-2186
	ETH.MESH.02227368	Meshes/Devices Chart	T-1192
	ETH.MESH.02219202	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock	T-1196
9/25/2012	ETH.MESH.08315779	Piet Hinoul Clinical Expert Report Gynecare Prolift +M Pelvic Floor Repair System	T-1205
1996	ETH.MESH.05795664	Ulmsten, U., et. Al. *An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence*	Smith T-0407 Smith T-0409
	ETH.MESH.05972834	Asset Purchase Agreement	Arnaurd T-0881
	ETH.MESH.08477464	Company Procedure for the Ethicon Product Development Process (PDP)	Smith T-0412
	ETH.MESH.03742864	Operating Procedure for Failure Modes and Effects Analysis Application (AFMEA) or Design (dFMEA)	Smith T-0413
	ETH.MESH.03742571	Company Procedure for Medical Device Risk Management Plan	Smith T-0414
	ETH.MESH.01268264	Risk Managent Report (legacy) for TVT and TVT-O	Smith T-0417
	ETH.MESH.03652924	Form for Internal Audit Corrective Action Plan	Smith T-0418
2/24/2006	ETH.MESH.00302105	Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary	Smith T-0419

	ETH.MESH.01310061	Risk Management report TVT Laser Cut Mesh (LCM)	Smith T-0420
	ETH.MESH.01310476	Risk Management report TVT Laser Cut Mesh (LCM)	Smith T-0421
1/29/2009	ETH.MESH.06858146	Email from Dan Smith re TVT-O resin Minute Jan 31th	Smith T-0242
	ETH.MESH.06858314	Test Method for the Thickness of Mesh	Smith T-0243
	ETH.MESH.08438961	Work instructions for Device Design Risk Management	Smith T-0244
2/14/2003	ETH.MESH.06873447	Due Diligence Growth Opportunity Outline	Smith T-0245
3/4/2003	ETH.MESH.00858094	Gynecare R&D Monthly Update - March	Smith T-0246
	ETH.MESH.00858092	Gynecare R&D Monthly Update - June	Smith T-0247
6/24/2003	ETH.MESH.02180737	Email from Ronnie Toddywala re Project Mulberry	Smith T-0248
			Smith T-0249
	ETH.MESH.03932909	History of TVT-O	Arnaud T-0842
	ETH.MESH.00857891	"Top Ten Reason To Pursue….Gynecare TVT Obturator System" PowerPoint Presentation by Brian Luscombe	Smith T-0250
	ETH.MESH.00858891	TVT proejcts charting document	Smith T-0251
1/22/2004	ETH.MESH.00857821	Gyecare TVT Obturator System Sales Training Launch Meeting	Smith T-0252
8/8/2003	ETH.MESH.03803462	Email from Laura Angelini re Transient Leg Pain with Mulberry	Smith T-0253
12/19/2003	ETH.MESH.00259473	TVT-O DDSA	Smith T-0254
3/29/2004	ETH.MESH.02180759	Letter from Jean de Leval	Smith T-0255
7/24/2003	ETH.MESH.00864101	Email from Dan Smith re TOVT development	Smith T-0256
8/8/2007	ETH.MESH.06861426	Email from Julie Hocknell re Adventures with TVT Secur	Smith T-0257
8/15/2003	ETH.MESH.00864131	Email from Brian Luscombe re Aug 11 program	Smith T-0258
	ETH.MESH.03926030	Meeting minutes re Project Scion	Smith T-0259
	ETH.MESH.00858096	Gynecare R&D Monthly Update - May	Smith T-0260
5/29/2003	ETH.MESH.00260020	Study Grid	Smith T-0261

6/17/2003	ETH.MESH.01815611	Email from Dan Smith re Discussion 11th June 2003	Smith T-0262
6/3/2003	ETH.MESH.00858175	Mulberry Weekly Meeting Minutes	Smith T-0263
1/16/2004	ETH.MESH.06164409	Email from Dan Smith re Dedication	Smith T-0264
2010	ETH.MESH.06260647	R&D CO-OP Welcome Guide Spring 2010	Smith T-0265
	ETH.MESH.01316727	Design History 1 book 1999 - TVT 5mm version	Smith T-0266
	ETH.MESH.01317508	Design History 1 book 1998 - TVT factbook	Smith T-0267
11/19/2010	ETH.MESH.00748213	TVT Classic IFU Revision Project Design Requirements Waiver Rationale Memo	Smith T-0422
	ETH.MESH.00858636	TVT Secur lessons learned review	Smith T-0426
7/18/2005	ETH.MESH.04939148	Corporate Product Characterization plan for Gynecare TVT S (Secur)	Smith T-0427
	ETH.MESH.01150009	Gynecare TVT Secur Presentation by Dan Smith	Smith T-0428
2007	ETH.MESH.06861473	Gynecare TVT Secur Competitive Product Update	Smith T-0429
	ETH.MESH.06860553	TVT & TVT Secur Documents	Smith T-0430
	ETH.MESH.04316544	Company Procedure for the Ethicon Product (PDP) - Design Controls	Smith T-0431
	ETH.MESH.00363605	Company Procedure for Design Changes to Existing Products	Smith T-0432
	ETH.MESH.05432198	Operating Procedure for Failure Modes and Effects Analysis Application (AFMEA) or Design (dFMEA)	Smith T-0433
10/7/2004	ETH.MESH.05456924	Email from Dan Smith to TVTx - Next Generation TVT "Project Initiation"	Smith T-0436
11/22/2004	ETH.MESH.00259042	2004 Strategy Tree Project Definition	Smith T-0437
	ETH.MESH.01217673	TVT-NEXT (TVTx) Development contract	Smith T-0438
4/25/2005	ETH.MESH.06274935	Email from Raimo Sump re TVT Secur Minutes - Team Meeting April 12 2005	Smith T-0439
	ETH.MESH.01410044	Gynecare TVT Secur Product Specs and changes	Smith T-0440
	ETH.MESH.05554367	Finger Pad Detail Drawings	Smith T-0441
	ETH.MESH.04385192	Gynecare TVT Secur Product Specs and changes	Smith T-0442
	ETH.MESH.05502894	Design Requirements Matrix - TVT S	Smith T-0443
	ETH.MESH.01592178	Design Validation Report - TVT S	Smith T-0444

	ETH.MESH.07876572	TVT Secure 510(k)	Smith T-0445
	ETH.MESH.02135955	Design Validation Report - TVT S	Smith T-0446
10/29/2007	ETH.MESH.00642325	Email from Kevin Mahar re TVT O versus TVT Secur efficacy and safety rate	Smith T-0447
7/28/2004	ETH.MESH.06869750	Human Cadaver Wetlab	Smith T-0448
2/8/2005	ETH.MESH.01037530	A 3 month pre-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model - Ethicon's Final Report	Smith T-0449
2005	ETH.MESH.00034720	A 3 month pre-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model - Published article	Smith T-0450
10/27/2004	ETH.MESH.05537701	Email from Walter Artibani re Results of TVTx preclinical trial	Smith T-0451
8/23/2005	ETH.MESH.00749504	Final Report, PSE Accession Number 05-0395, Project Number 67379: Evaluation of fixation force for the Gynecare TVT Secur Device in a sheep cadaver pelvic floor model	Smith T-0452
8/23/2005	ETH.MESH.00749518	Final Report, PSE Accession Number 05-0396, Project Number 67379: Evaluation of the Pullout Force of Gynecare TVT Secur implanted into the urogenital diaphragm and obturator membrane of a human cadaver	Smith T-0453
12/2/2005	ETH.MESH.03714002	Clinical Expert Report - Gynecare TVT Secur System	Smith T-0454
	ETH.MESH.00853802	Medical device risk management/company procedure for Medical Device Risk Management Plan: PR602-003	Smith T-0457
	ETH.MESH.00538202	A Pilot Study of the Gynecare TVT Secur System for Treatment of Stress Urinary Incontinence	Smith T-0458
11/21/2005	ETH.MESH.00752863	Gynecare TVT Secur - Manufacture and subsequent operations of the Inserter Body	Smith T-0459
11/22/2005	ETH.MESH.03648795	Gynecare TVT Secur - Inserter Assembly Welded	SmithT-0460

6/6/2006	ETH.MESH.0109412	Process at Ethicon Sarl and Ethicon BmbH for the TVT Secur System	Smith T-0461
5/18/2006	ETH.MESH.0554680	Email from Risa Cantimbuhan re Design Transfer checklist discussion	Smith T-0462
	ETH.MESH.05534022	aFMEA for TVT Secur - CO-0011927 change	Smith T-0463
	ETH.MESH.00823549	aFMEA for TVT Secur - Additional Change	Smith T-0464
	ETH.MESH.05534…	Design GMEA for TVT Secur, Version 1, FMEA-00002680	Smith T-0465
	ETH.MESH.01407837	PFMEA-100152	Smith T-0466
	ETH.MESH.00752921	Risk Management Report TVT Secur Revision A	Smith T-0467
	ETH.MESH.00752928	Risk Management Report TVT Secur Revision B	Smith T-0468
	ETH.MESH.00752933	TVT Secur Harms/Hazards table Version A	Smith T-0469
	ETH.MESH.05534013	Risk Management Report: TVT Secur	Smith T-0470
6/20/2003	ETH.MESH.01814371	Email from Katrin Elbert re Design Control	Smith T-0221
	ETH.MESH.01814384	Work Instruction for New Product Design Control	Smith T-0222
3/16/2004	ETH.MESH.03364540	Email from Dan Smith re TVTO training Carmel Ramage	Smith T-0229
8/18/2004	ETH.MESH.06884516	Email from Kevin Mahar re Dr. Jensen Follow up	Smith T-0230
6/2/2003	ETH.MESH.00862727	Email from Dan Smith re My notes from the Thursday evening presentation 5/22/03 and Friday's surgery	Smith T-0231 Arnaud T-0851
6/22/2004	ETH.MESH.06881589	Email from Janice Burns re Gynecare TVT Oburator Global Launch Update - Issue 4	Smith T-0232
8/17/2004	ETH.MESH.01815505	Email from Janice Burns re TVTO Dr. Feagins case follow up	Smith T-0233
9/8/2004	ETH.MESH.06884726	Email from Shannon Campbell re Ongoing TVT-O Action Items	Smith T-0234
9/14/2004	ETH.MESH.00864493	Email from Dan Smith re Ongoing TVT-O Action Items	Smith T-0235
8/17/2004	ETH.MESH.06881576	Email from Janice Burns re TVTO	Smith T-0237
5/5/2004	ETH.MESH.00864407	Email from Dan Smith re TVT-O	Smith T-0238

2/19/2004	ETH.MESH.06892171	Email from Dan Smith re TVT-O recognition Submission JANICE FOR YOUR COMMENTS!!!!!!!!	Smith T-0239
9/8/2004	ETH.MESH.00864490	Email from Dan Smith re Ongoing TVT-O Action Items	Smith T-0240
2/20/2003	ETH.MESH.03911107	Email from Axel Arnaud re TVT complications (an Prof. Hausler)	Arnaud T-0835
7/21/2004	ETH.MESH.03910799	Email from Axel Arnaud re TVT Erosions?	Arnuad T-0836
11/28/1999	ETH.MESH.03917309	Email from Rodrigo Bianchi re TVT event	Arnuad T-0839
1/31/2006	ETH.MESH.03911712	Email from Axel Arnaud re TVT - TVT-O Specifications	Arnaud T-0840
6/6/2003	ETH.MESH.03907853	Email from Laure Le Treguilly re TVT - Serious Complication	Arnaud T-0841
	ETH.MESH.03907468	Second Generation TVT	Arnaud T-0843
	ETH.MESH.03907327	Trans-obturator TVT - Procedure In-Out Pr J. de Leval (University of Liege, Belgium)	Arnaud T-0844
5/25/2003	ETH.MESH.03910890	Email from Axel Arnaud re Follow up Mulberry	Arnaud T-0845
6/9/2003	ETH.MESH.00261584	Email from Sean O'Bryan re Mulberry stage gate action item closed	Arnaud T-0846
8/14/2003	ETH.MESH.03911390	Email from Axel Arnaud re Transient leg pain with Mulberry	Arnaud T-0847
1/7/2009	ETH.MESH.01202101	Email from Aaron Kirkemo re My revised writeup of the DeLeval and Waltregny visit	Arnaud T-0848
2/20/2006	ETH.MESH.03938897	Email from Xavier Buchon re Pr Cosson	Arnaud T-0849
3/26/2003	ETH.MESH.03919404	Email from Axel Arnaud re Mulberry	Arnaud T-0850
6/1/2009	ETH.MESH.00860142	Email from Dan Smith re Sample Medio TVTO	Arnaud T-0852
	ETH.MESH.02340568	TVT-S IFU	Arnaud T-0853
1999	ETH.MESH.04193990	Major Executive Committee Actions	T-0358
	ETH.MESH.00826057	"Gynecare TVT Secur Project Overview"	T-0729
11/30/2006	ETH.MESH.03921612	Emial from Ralf Felix Gotter re The more procedures the more problems	Arnaud T-0855
12/5/2006	ETH.MESH.03921580	Email from Dan Smith re TVT-Secur follow up conference call last week	Arnaud T-0856

12/15/2006	ETH.MESH.01770534	Email from Axel Arnaud re TVT-S Cookbooks	Arnaud T-0857
	ETH.MESH.01770535	"TVT-Secur: 'Hammock' Position"	Arnaud T-0858
	ETH.MESH.01770541	"TVT-Secur: 'U' Position"	Arnaud T-0859
12/19/2006	ETH.MESH.01000731	Email from David Robinson re TVT-S Cookbooks	Arnaud T-0860
12/19/2006	ETH.MESH.00519476	Email from Dan Smith re TVT-S Cookbooks	Arnaud T-0861
12/19/2006	ETH.MESH.03921499	Email from David Robinson re TVT Secur	Arnaud T-0862
12/20/2006	ETH.MESH.01784428	Email from David Robinson re TVT-S Cookbooks	Arnaud T-0863
1/8/2007	ETH.MESH.03912639	Email from Axel Arnaud re TVT Cookbooks	Arnaud T-0864
	ETH.MESH.03912647	Document re TVT procedure	Arnaud T-0865
1/9/2007	ETH.MESH.04204341	Email from Harel Gadot re report from Austria	Arnaud T-0866
	ETH.MESH.04204343	Women's Health - Monthly Report December 06	Arnaud T-0867
1/10/2007	ETH.MESH.03922966	Email from David Robinson re Report from Austria	Arnaud T-0868
1/16/2007	ETH.MESH.03922950	Email from David Robinson re TVT Secur procedural steps	Arnaud T-0869
3/9/2007	ETH.MESH.01000323	Email from Dan Smith re DRAFT of the latest "cookbook" after my trip to Germany	Arnaud T-0870
	ETH.MESH.01000449	Gynecare TVT Secur System Key Technical Points (Procedural Pearls)	Arnaud T-0871
5/4/2007	ETH.MESH.00163952	Gynecare TVT Secur System Key Technical Points	Arnaud T-0872
5/22/2007	ETH.MESH.00527832	Email from Dan Smith re TVT SECUR EU Experts Meeting - feedback & future actions	Arnaud T-0873
	ETH.MESH.00158289	TVT Secur Patient Brochure	Arnaud T-0875
1/16/2007	ETH.MESH.03922953	Email from Xavier Buchon re French data on TVT Secur	Arnaud T-0876
6/6/2007	ETH.MESH.03922405	Email from Andrew Beveridge re TVT Secur & NICE	Arnaud T-0877
10/3/2007	ETH.MESH.03922261	Email from Andrew Beveridge re AMS mini arc	Arnaud T-0878
11/15/1999	ETH.MESH.06692673	Ulmsten & Ethicon Consulting Agreement	Arnaud T-0882
10/17/1997	ETH.MESH.08476335	Scandinavian Multicenter Study of the tension free vaginal tape procedure	Arnaud T-0883

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5/1/2008	ETH.MESH.08385338	Technical Memo Project Nuvance	Trzewik T-3234
	ETH-00295	Gynecare Prolift IFU	Tzewik T-3237
	ETH.MESH.02342194	Gynecare Gynemesh PS IFU	Trzewik T-3238
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	ETH.MESH.09645766	When the Implant Worries the Body presentation	Trzewik T-3243
	ETH.MESH.02588182	Exploratory Program "Thunder" presentation by Trzewik and Meier	Trzewik T-3244
1/8/2009	ETH.MESH.09656632	Biomechanical consideration presentation	Trzewik T-3245
	ETH.MESH.09652185	Today's vaginal implants do not consider the patients' biomechanical needs	Trzewik T-3246
8/1/2006	ETH.MESH.05454207	Email from Juergen Trzewik to Peter Meier re fotos cadevar lab	Trzewik T-3247
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	ETH.MESH.09279097	Prolene Mesh Improvement Project	
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5/6/2005	ETH.MESH.00526473	Email from Allison London Brown re laser-cut mesh	

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Date	Deponent
02/28/2012	
02/29/2012	Cliff Volpe
04/05/2012	
04/06/2012	
09/18/2012	
06/29/2013	
06/27/2013	Piet Hinoul
03/13/2012	
03/14/2012	
08/23/2012	
09/11/2013	David Robinson
3/9/2012	Sunny Rha
4/18/2012	Aaron Kirkemo
5/18/2012	Sean O'Bryan
03/29/2012	
03/30/2012	
12/03/2012	Scott Ciarrocca
03/27/2012	
03/28/2012	Vincenza Zaddem
2/24/2012	Elizabeth Vailhe
06/20/2013	
06/21/2013	Christophe Vailhe
07/29/2013	
07/30/2013	Joerg Holste
08/01/2013	
08/02/2013	Boris Batke
10/02/2012	
05/22/2013	
05/23/2013	Daniel Burkley

10/09/2012
10/10/2012
08/14/2013
08/15/2013 Thomas Barbolt
09/11/2013
09/12/2013 Brigitte Hellhammer
09/18/2013
09/19/2013 Juergen Trzewik
5/31/2013 Martin Weisberg
9/25/2013 Axel Arnaud
05/15/2013
05/16/2013
06/04/2013
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08/20/2013
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7/29/2013		Snippet from Joerg Holste Deposition	

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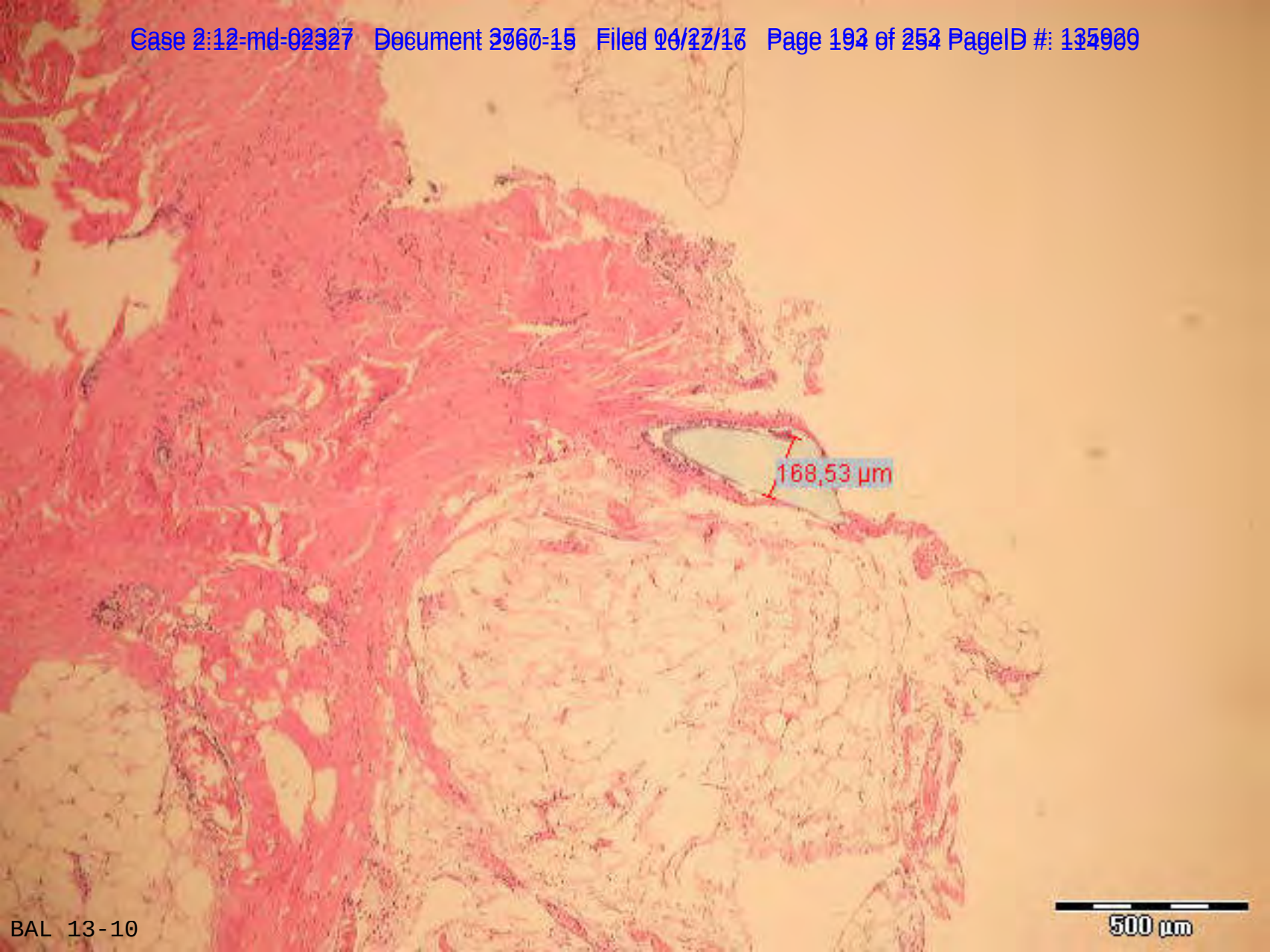
Name	Date
Expert Report of Dr. Howard Jordi	10/12/2013
Expert Report of Prof. Thomas Muehl	10/11/2013

EXHIBIT

C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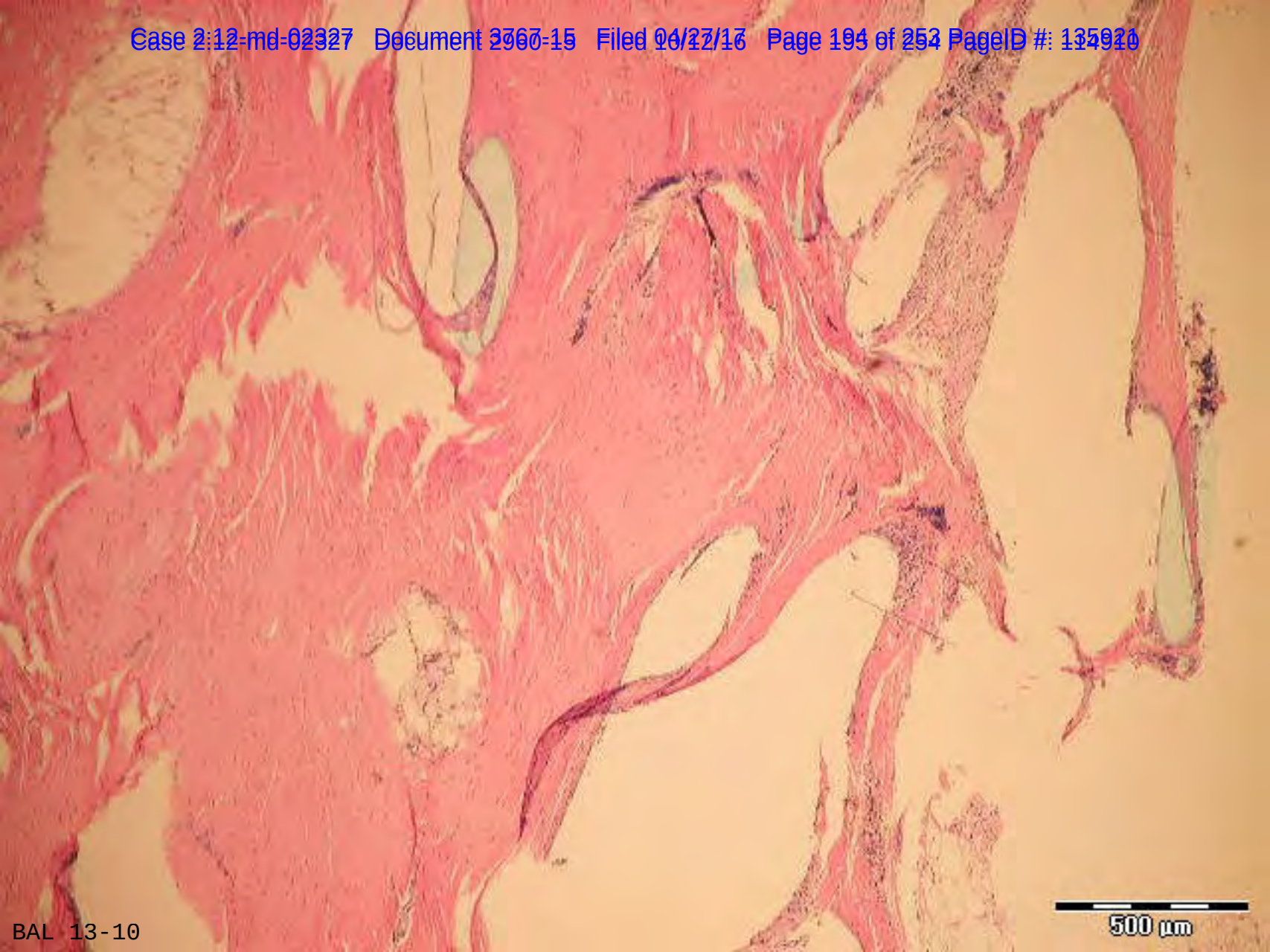

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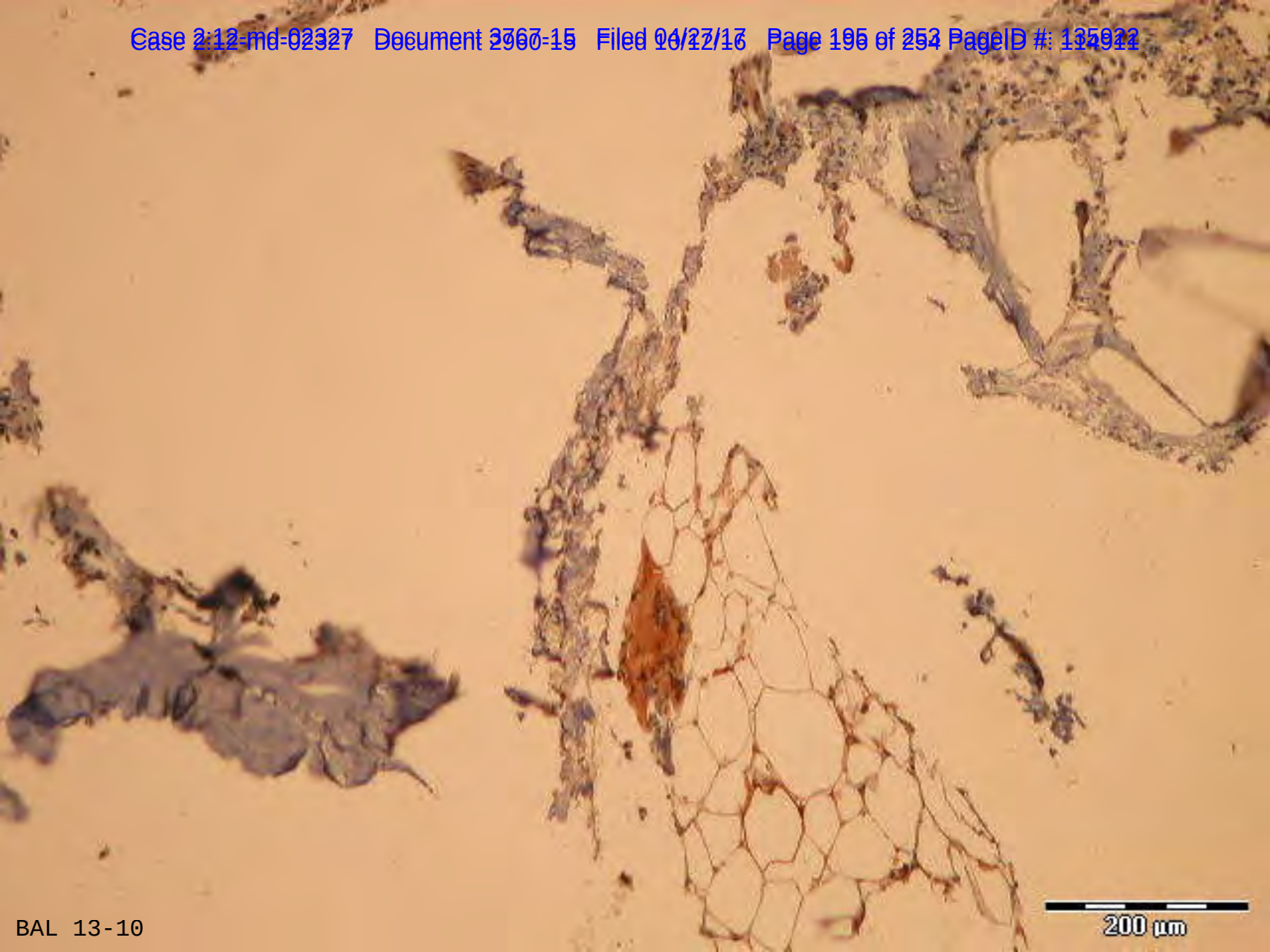
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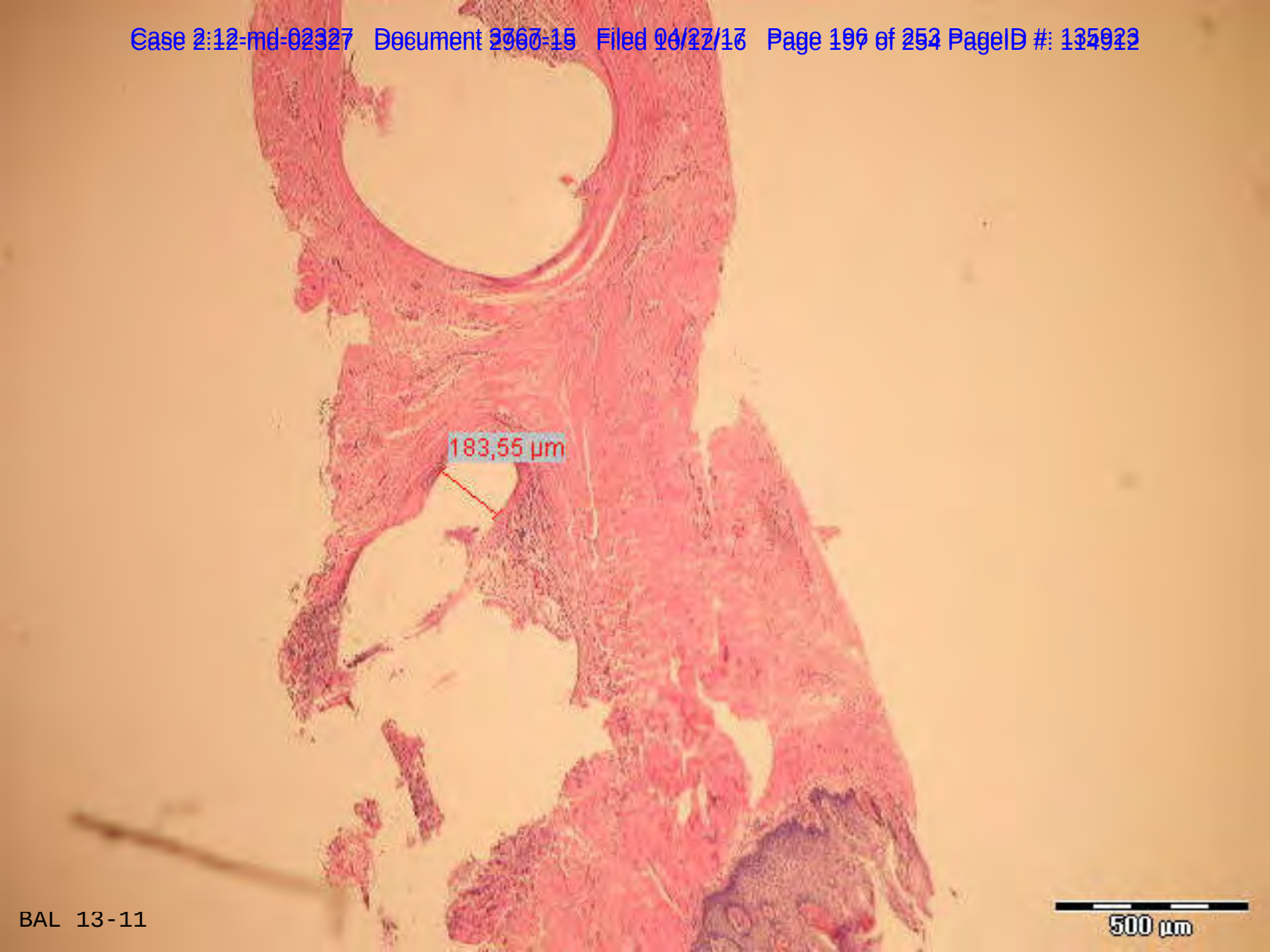
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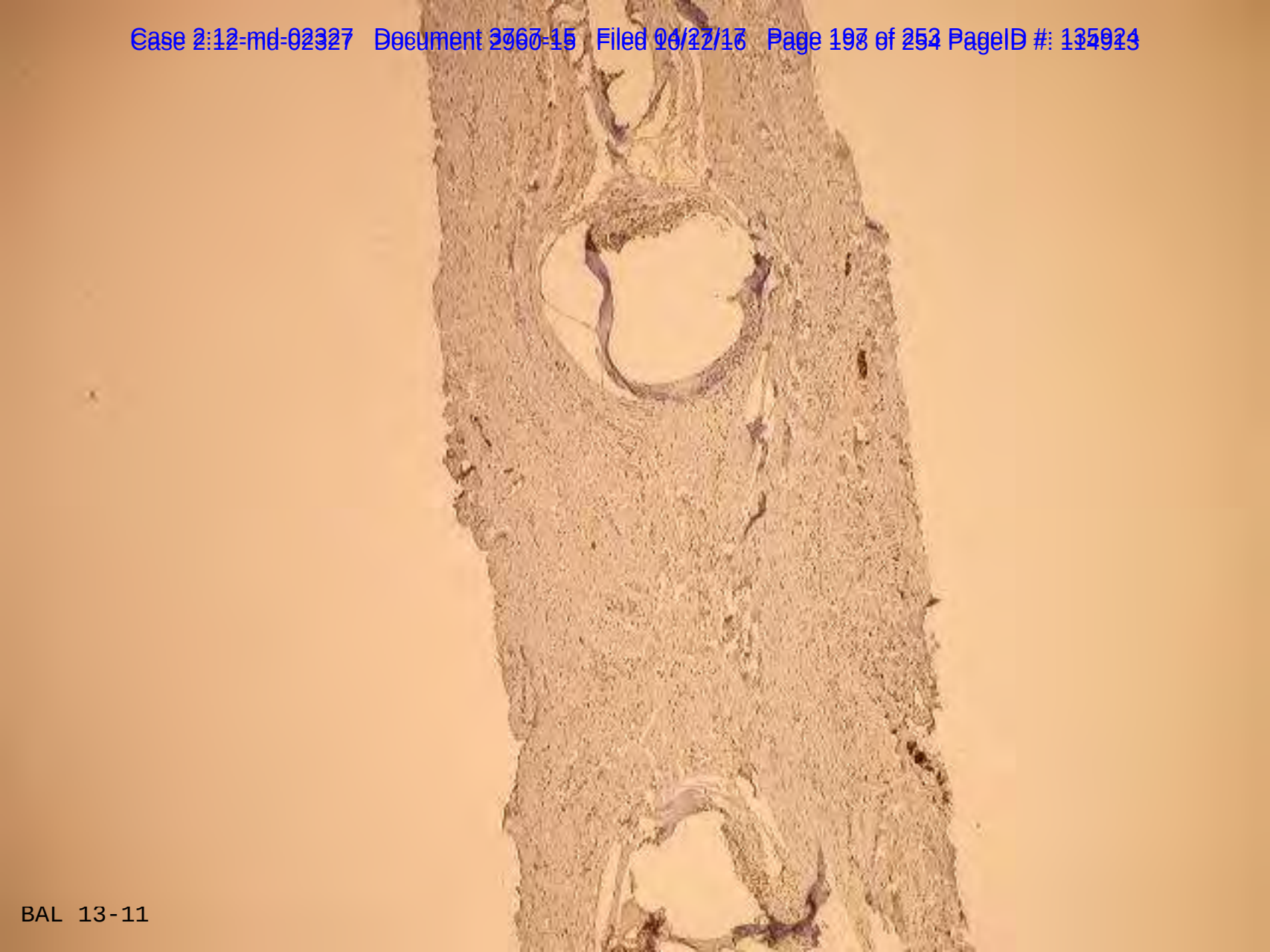

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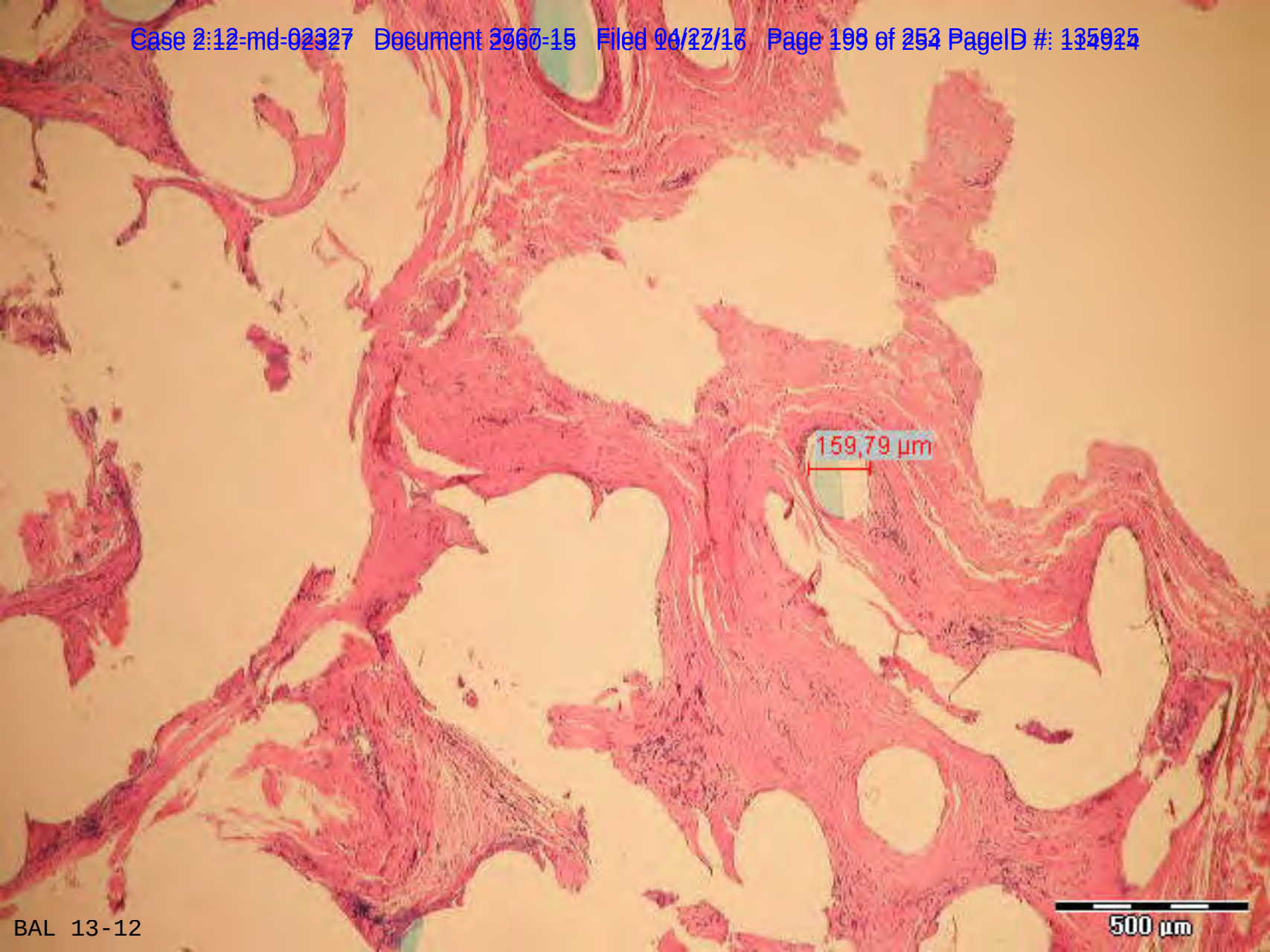
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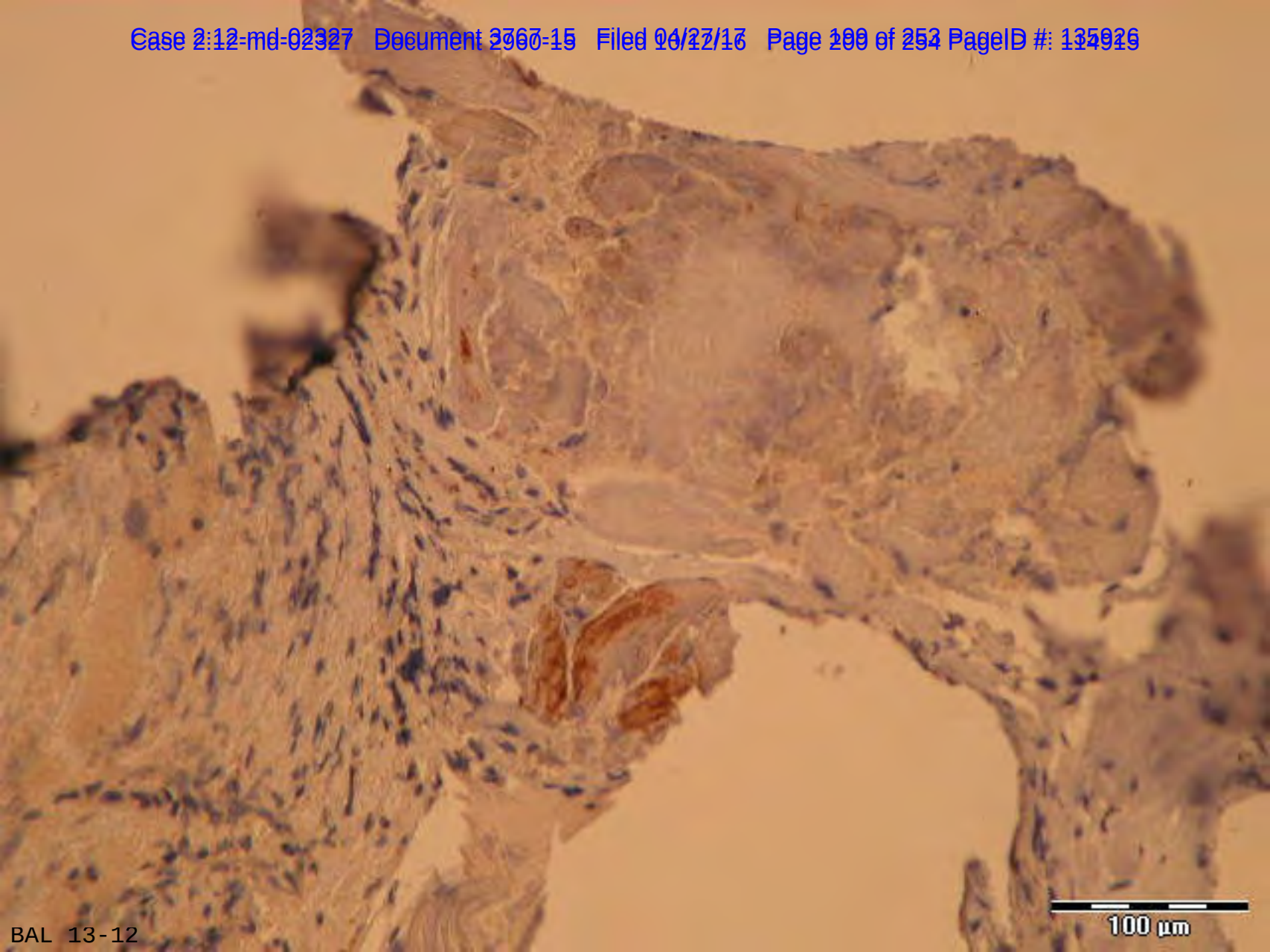
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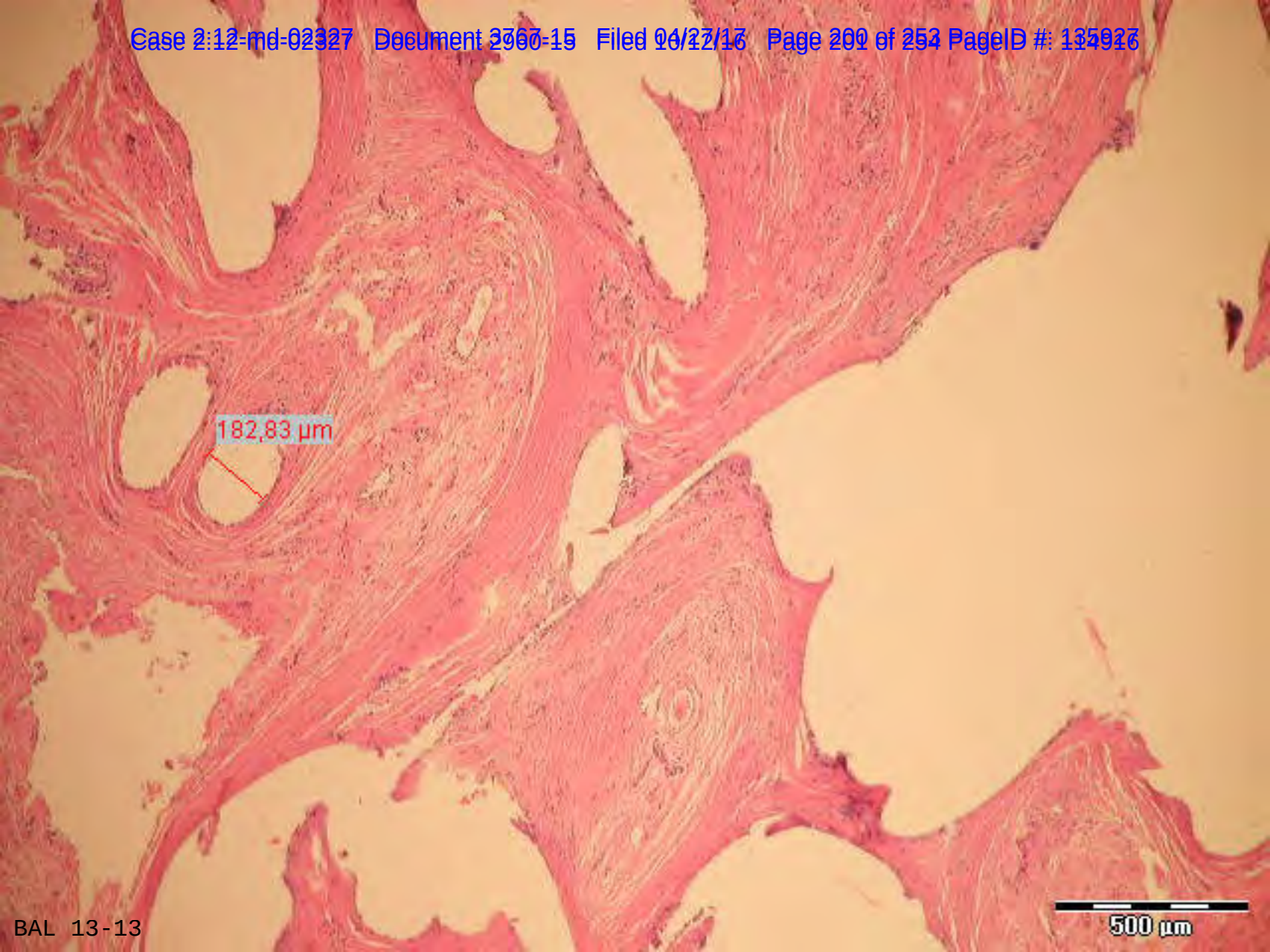

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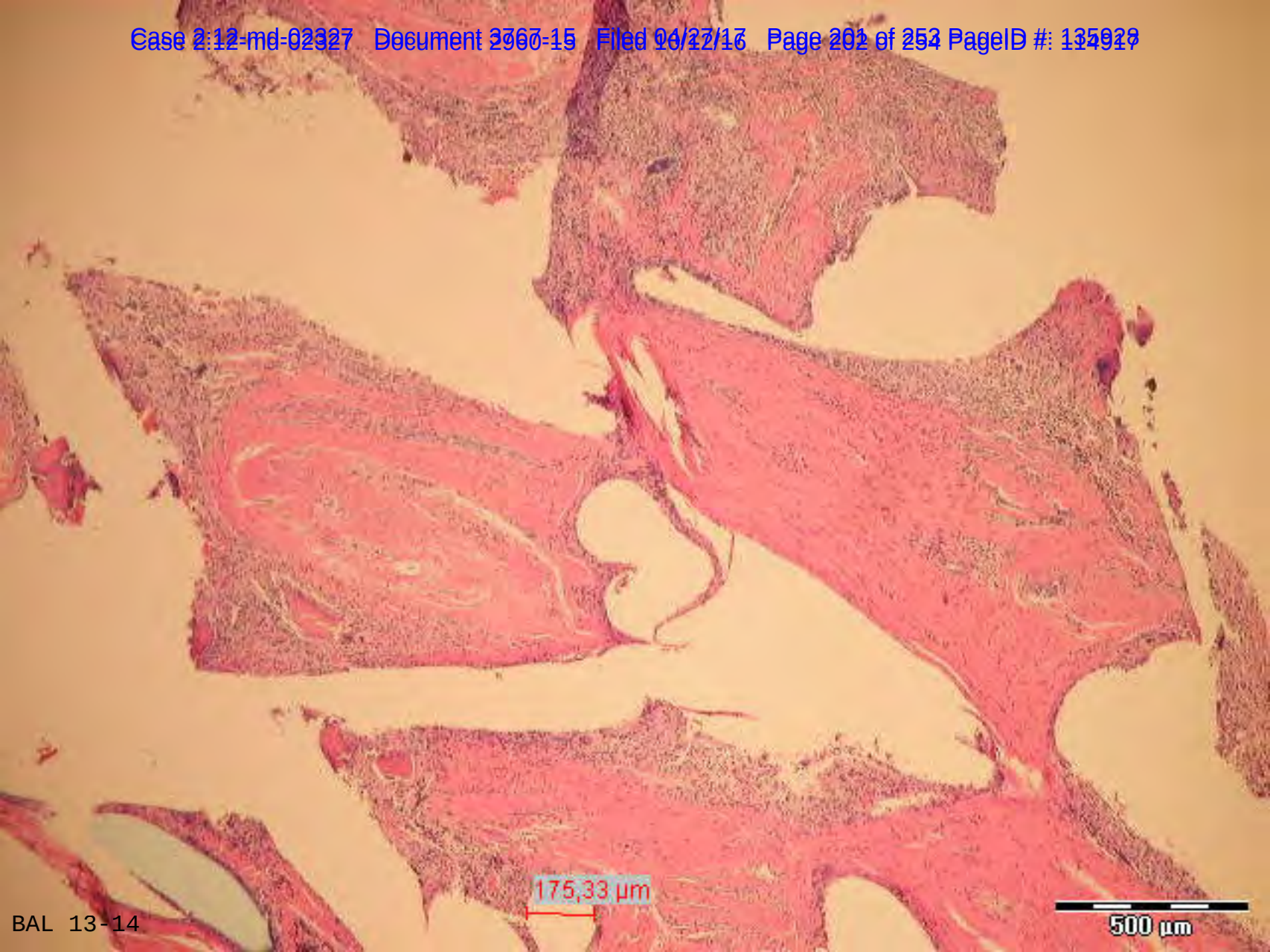
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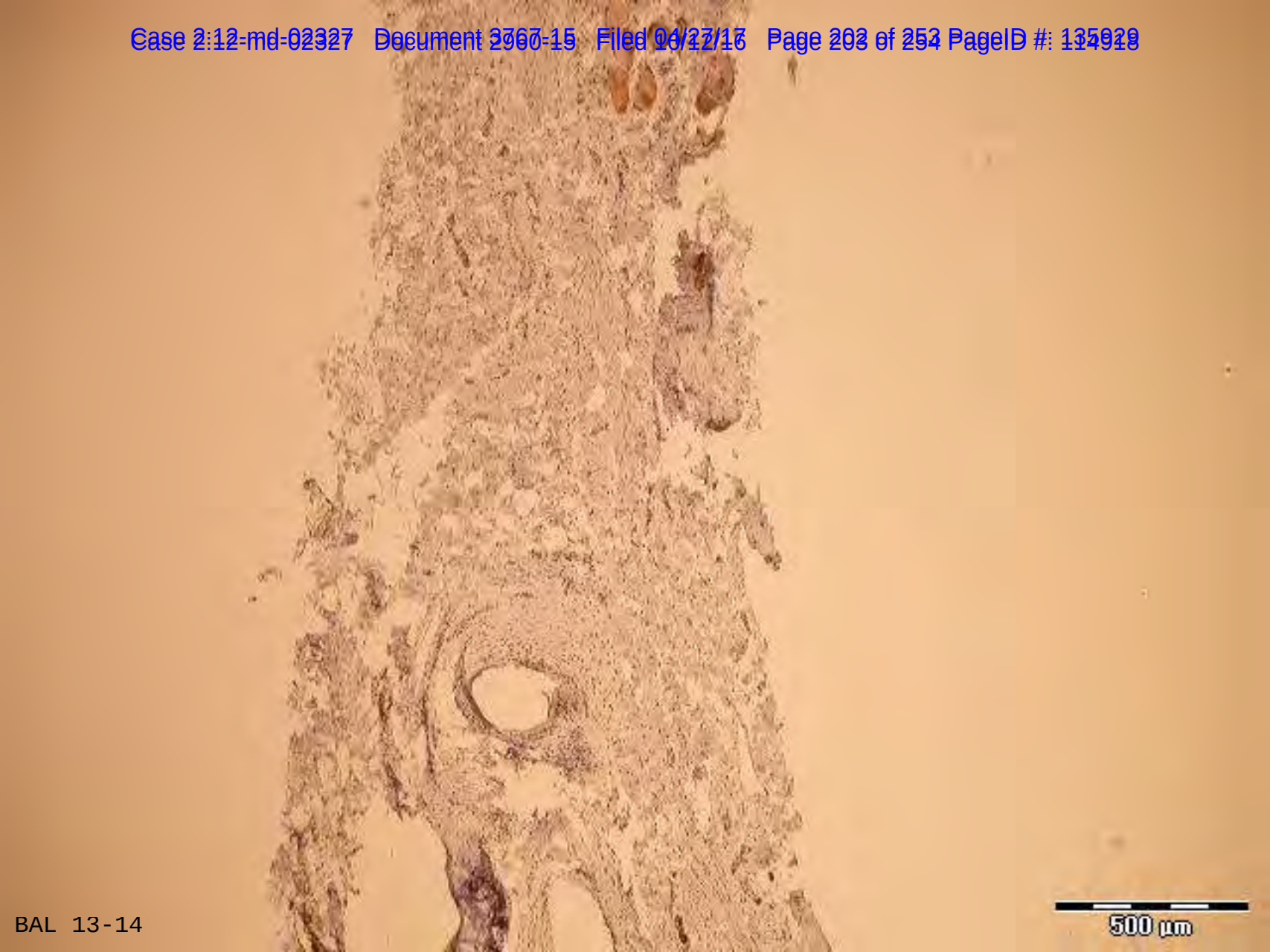

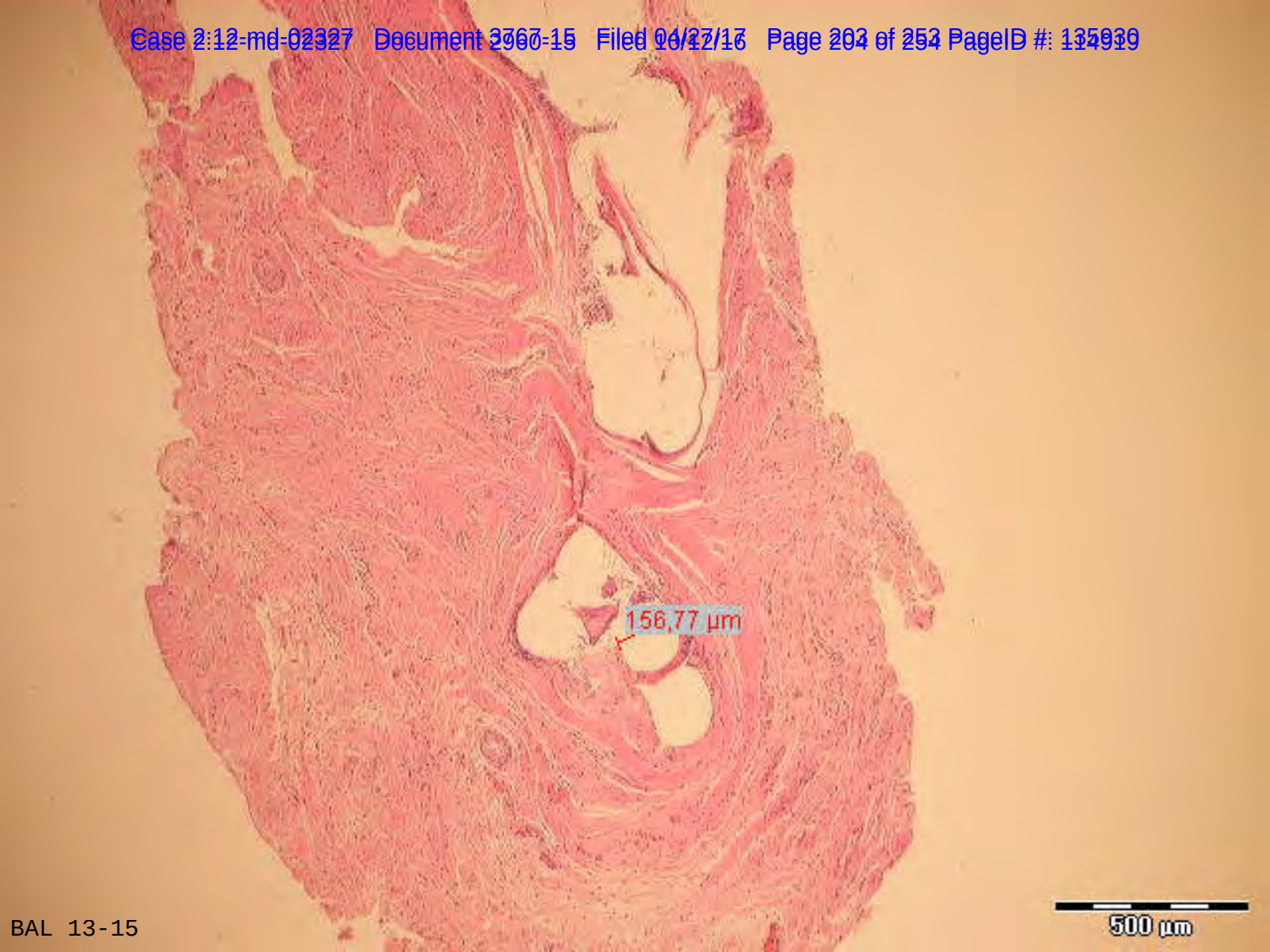

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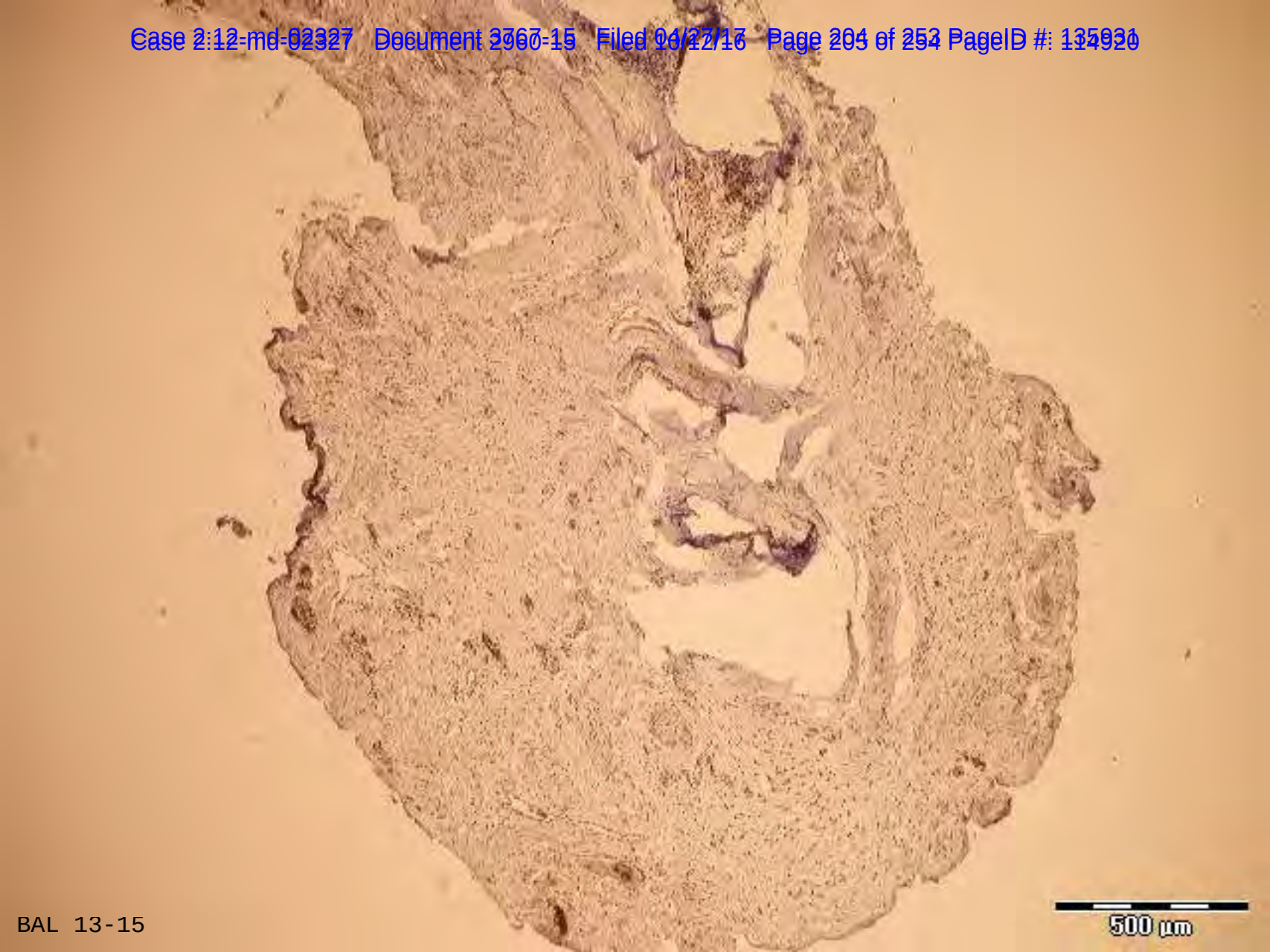
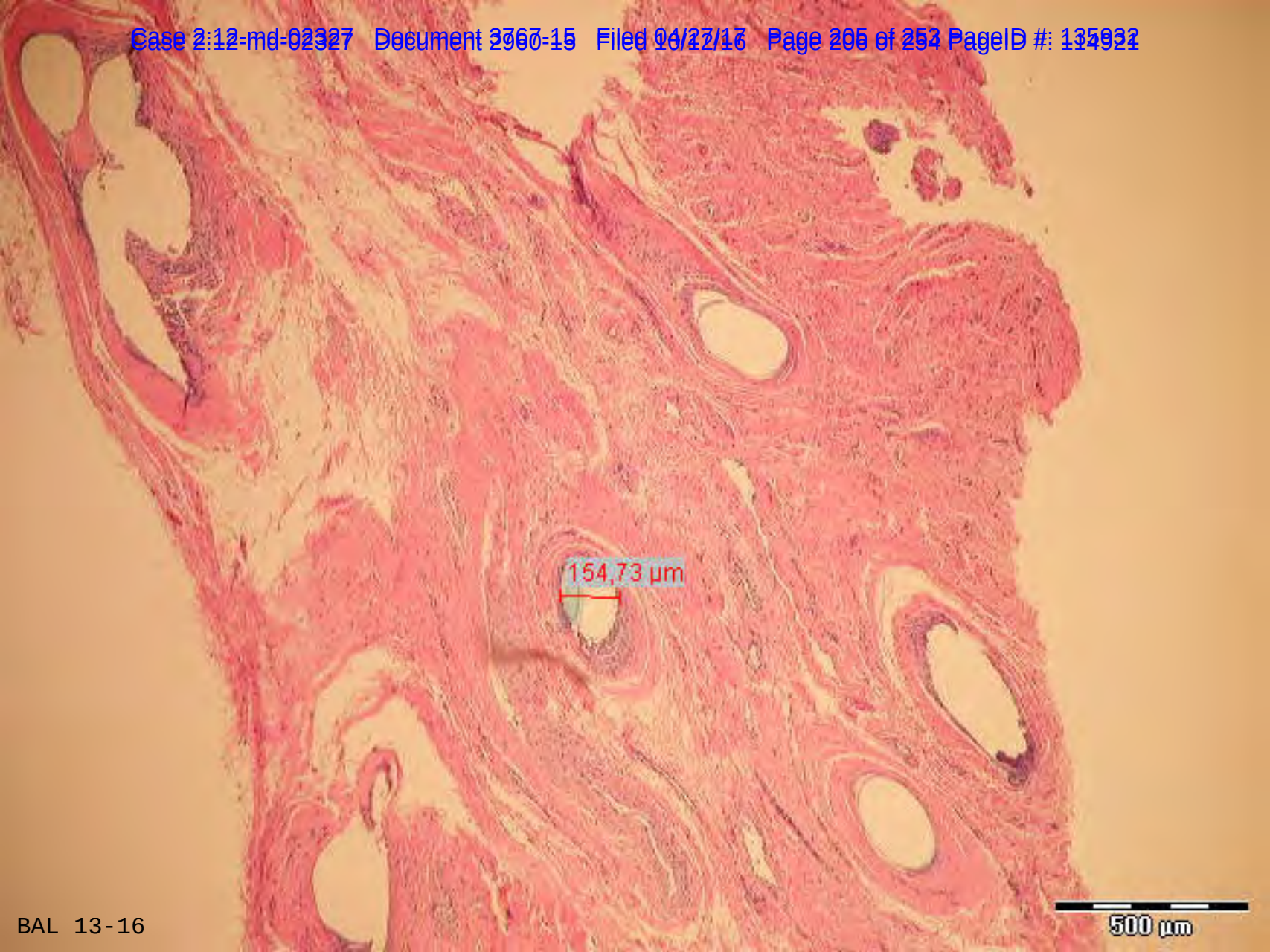
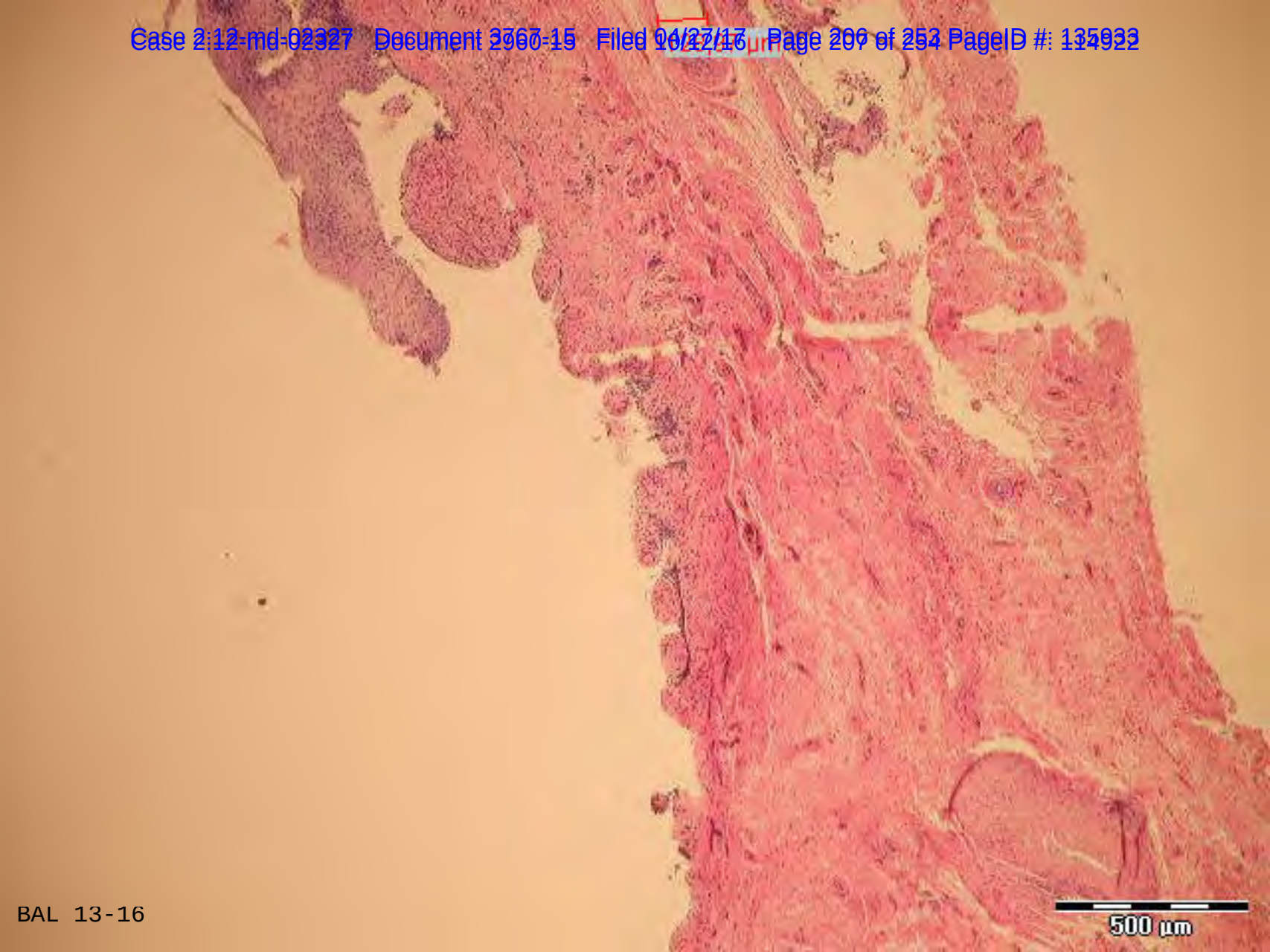


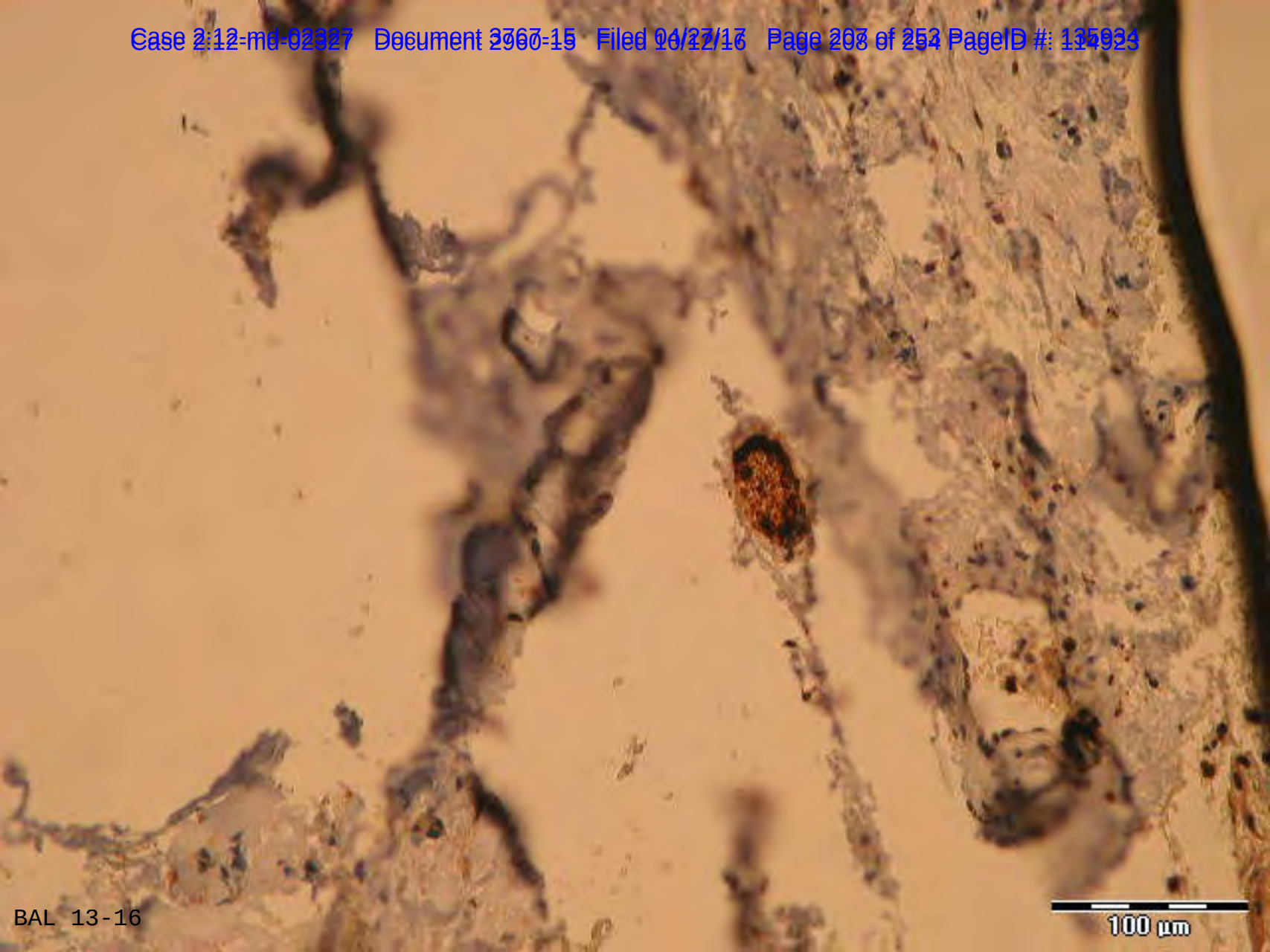
BAL 13-15

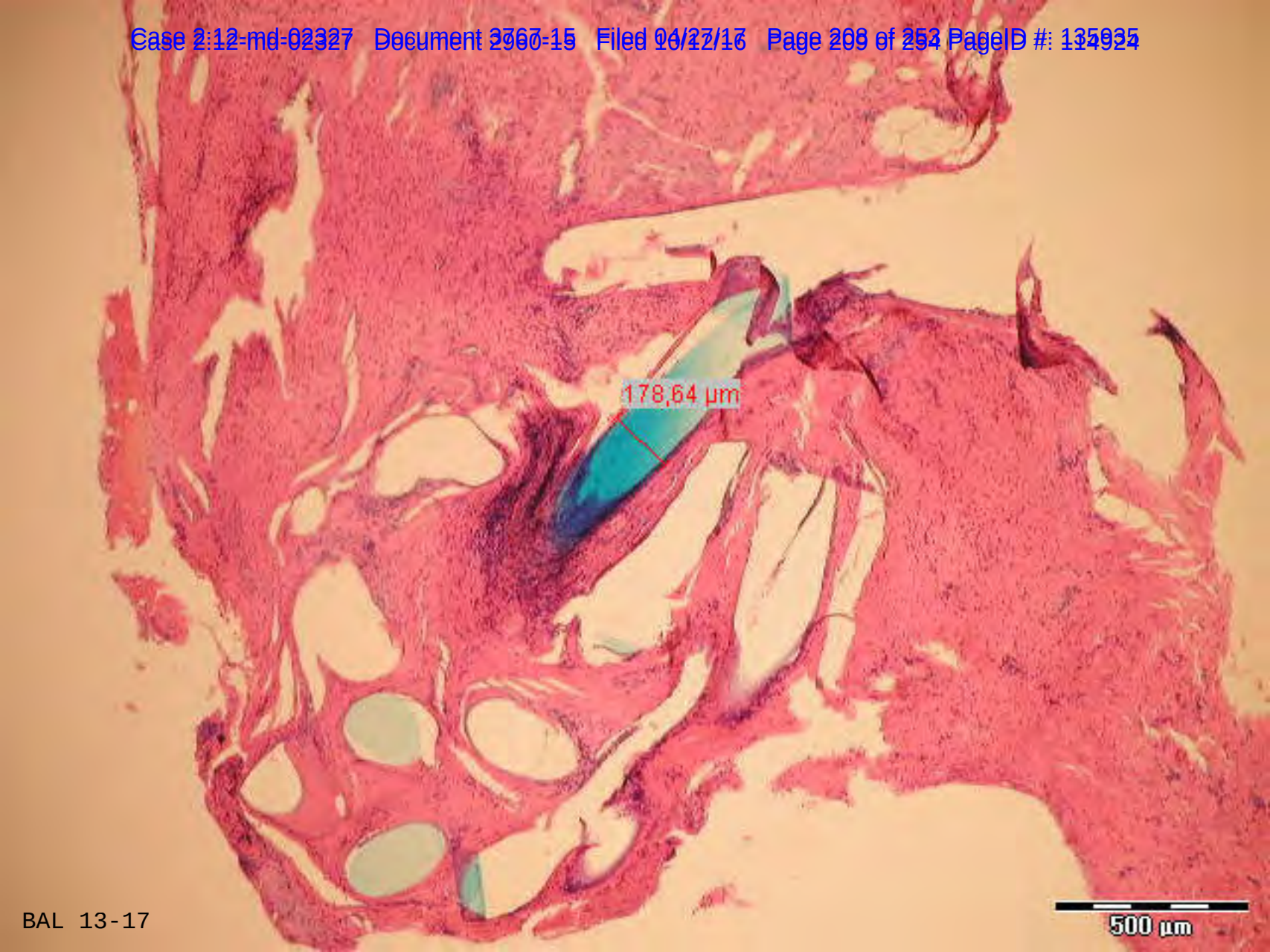


BAL 13-16

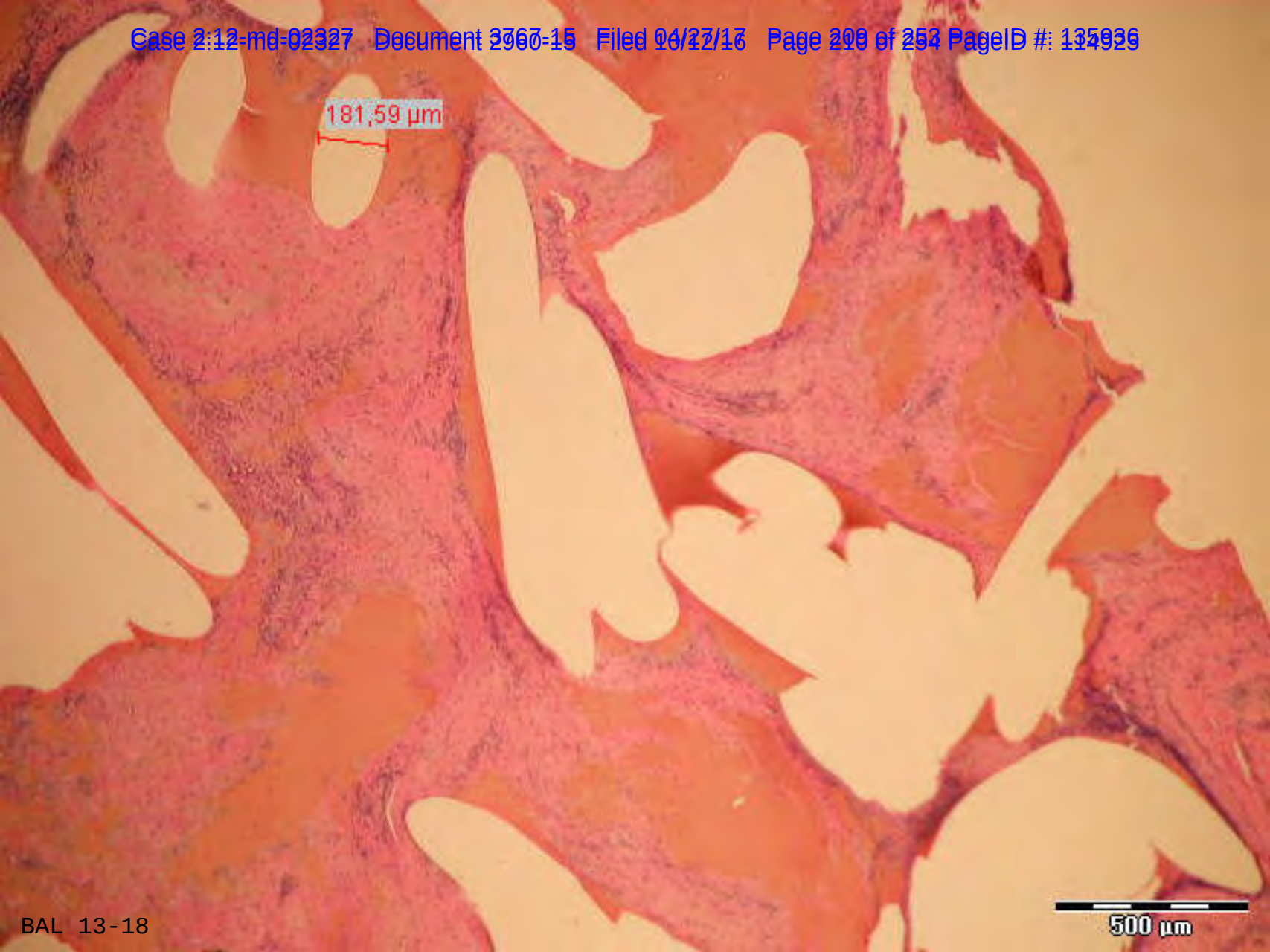


BAL 13-16

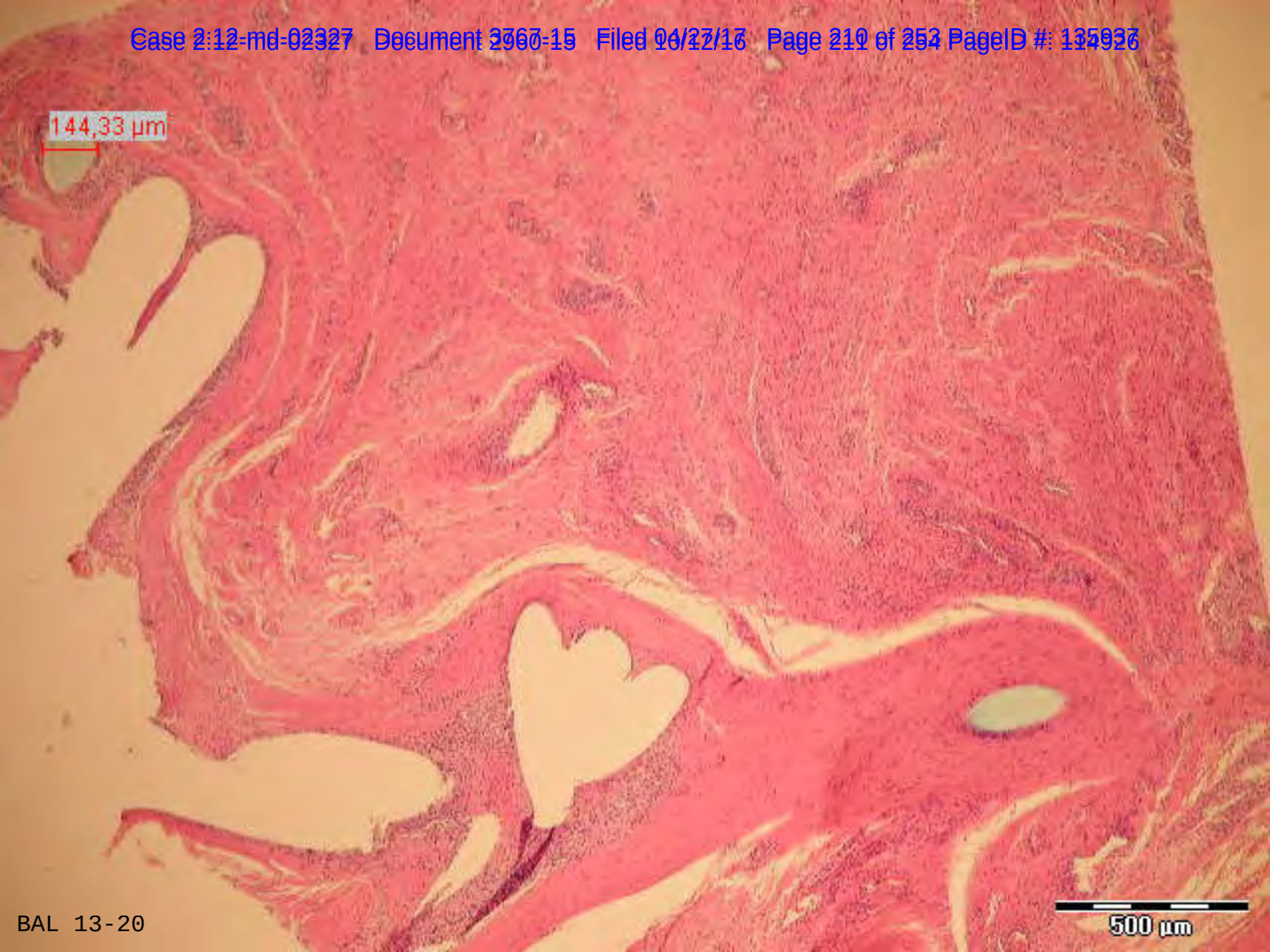

BAL 13-16
100 µm



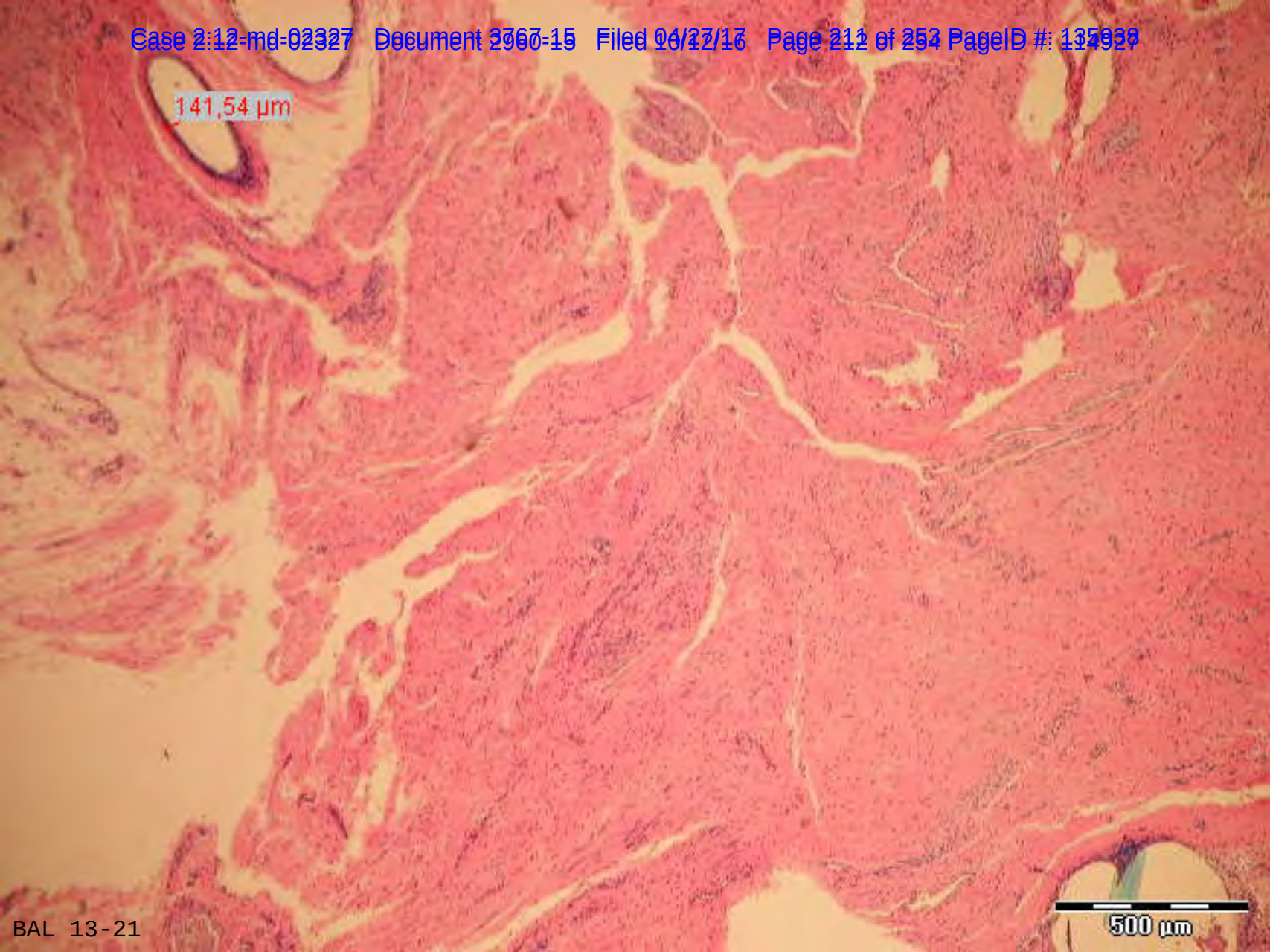
BAL 13-17

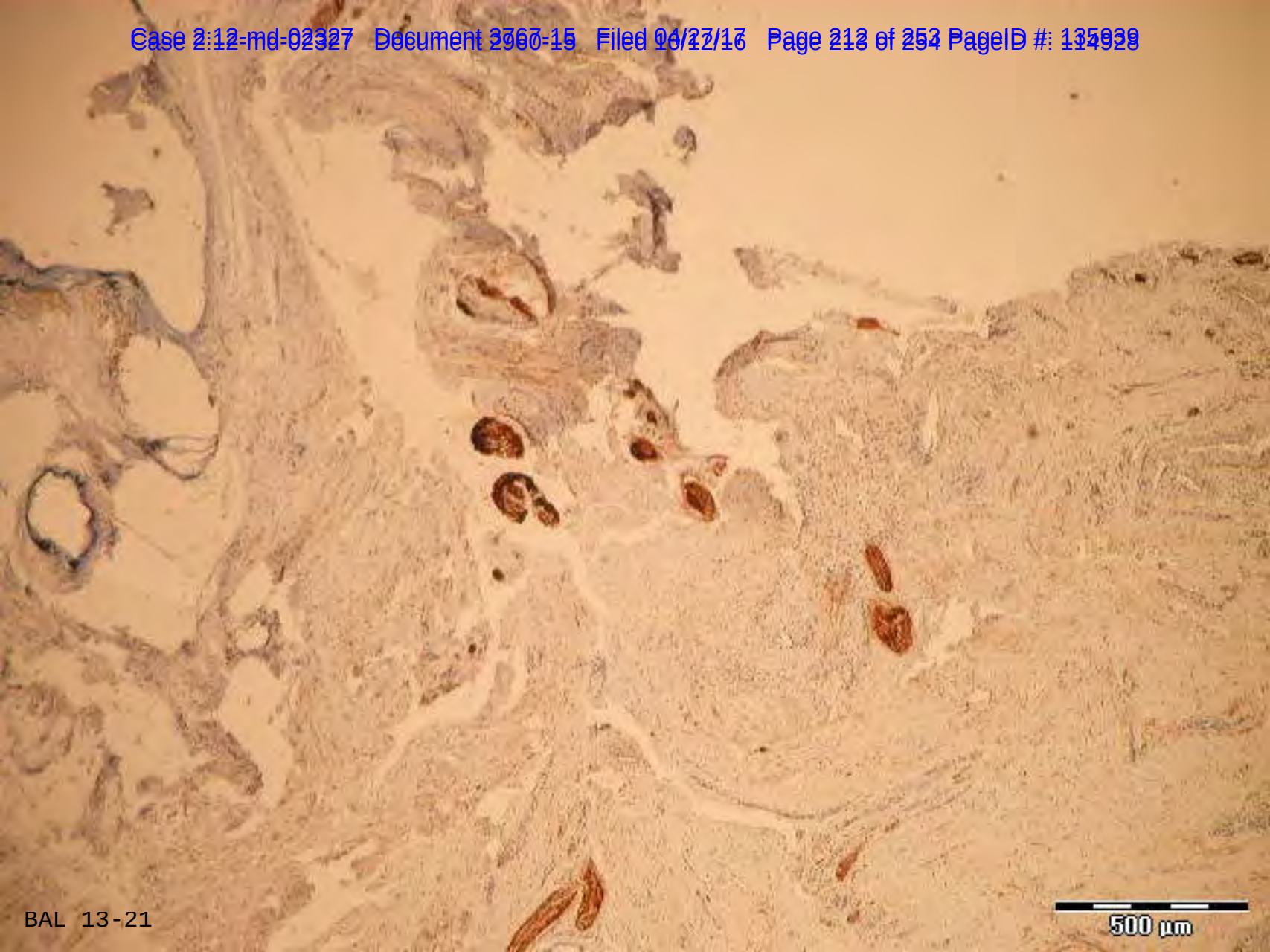


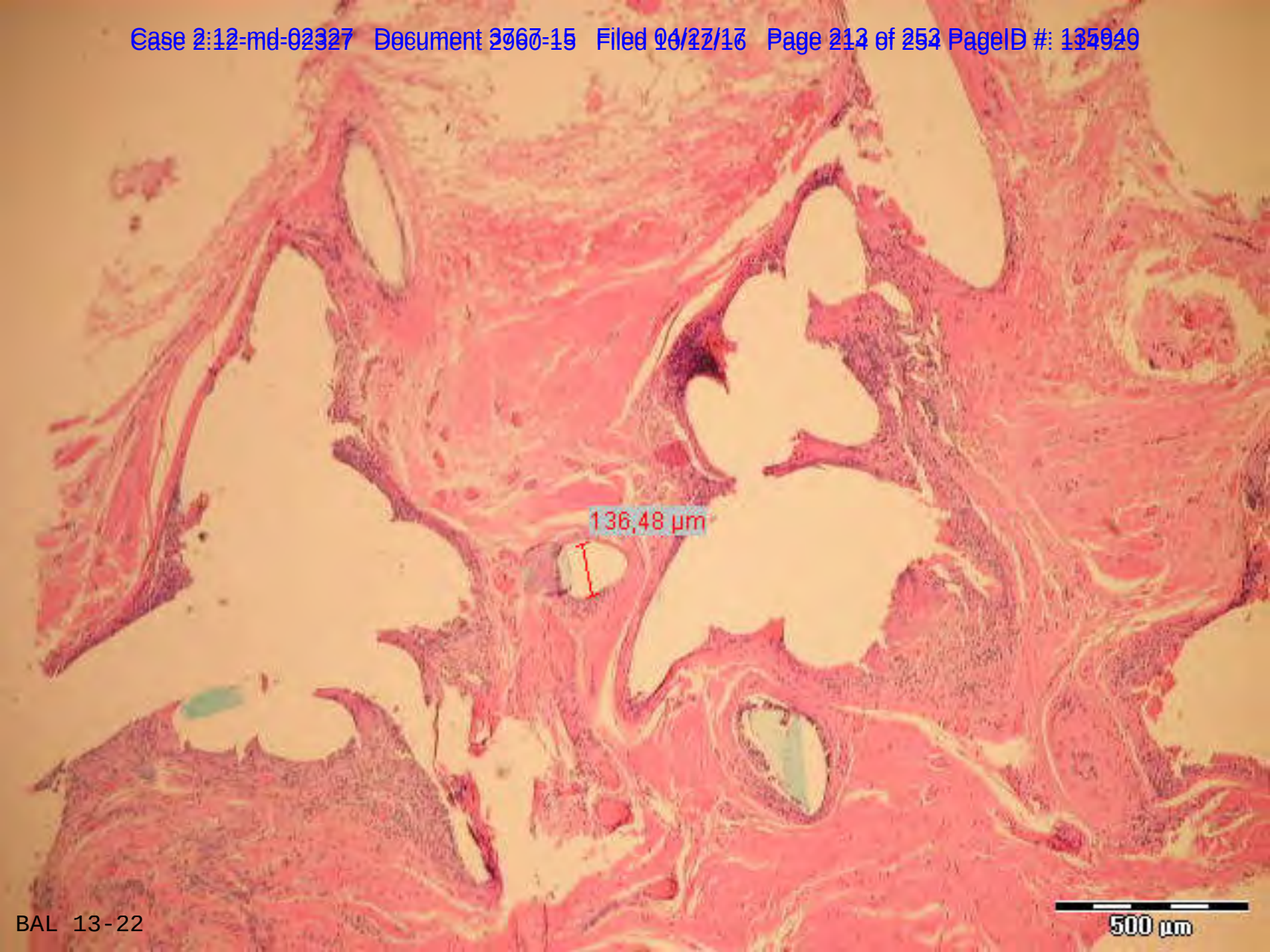
BAL 13-18



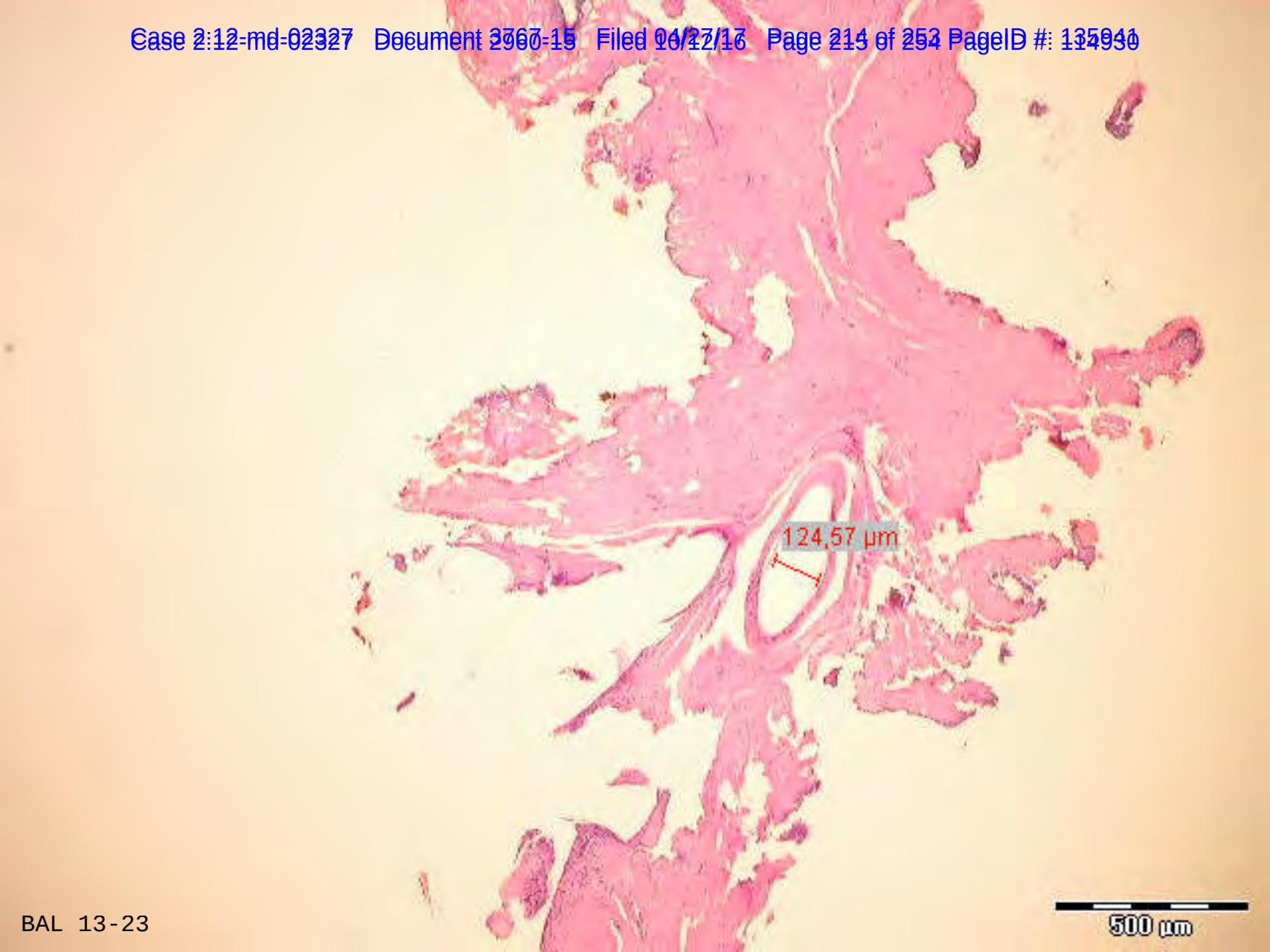
BAL 13-20


141,54 µm
500 µm
BAL 13-21

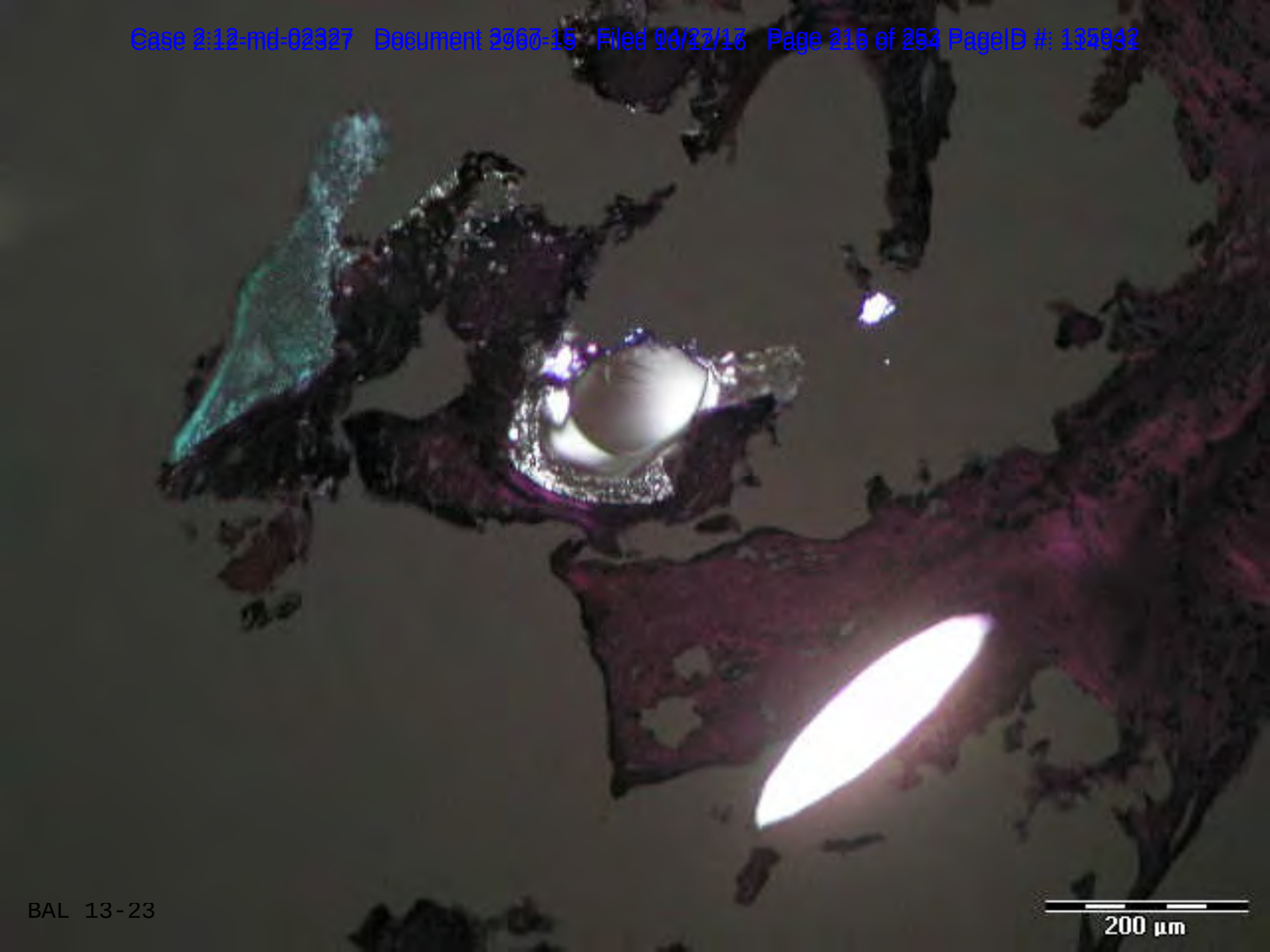

BAL 13-21
500 µm

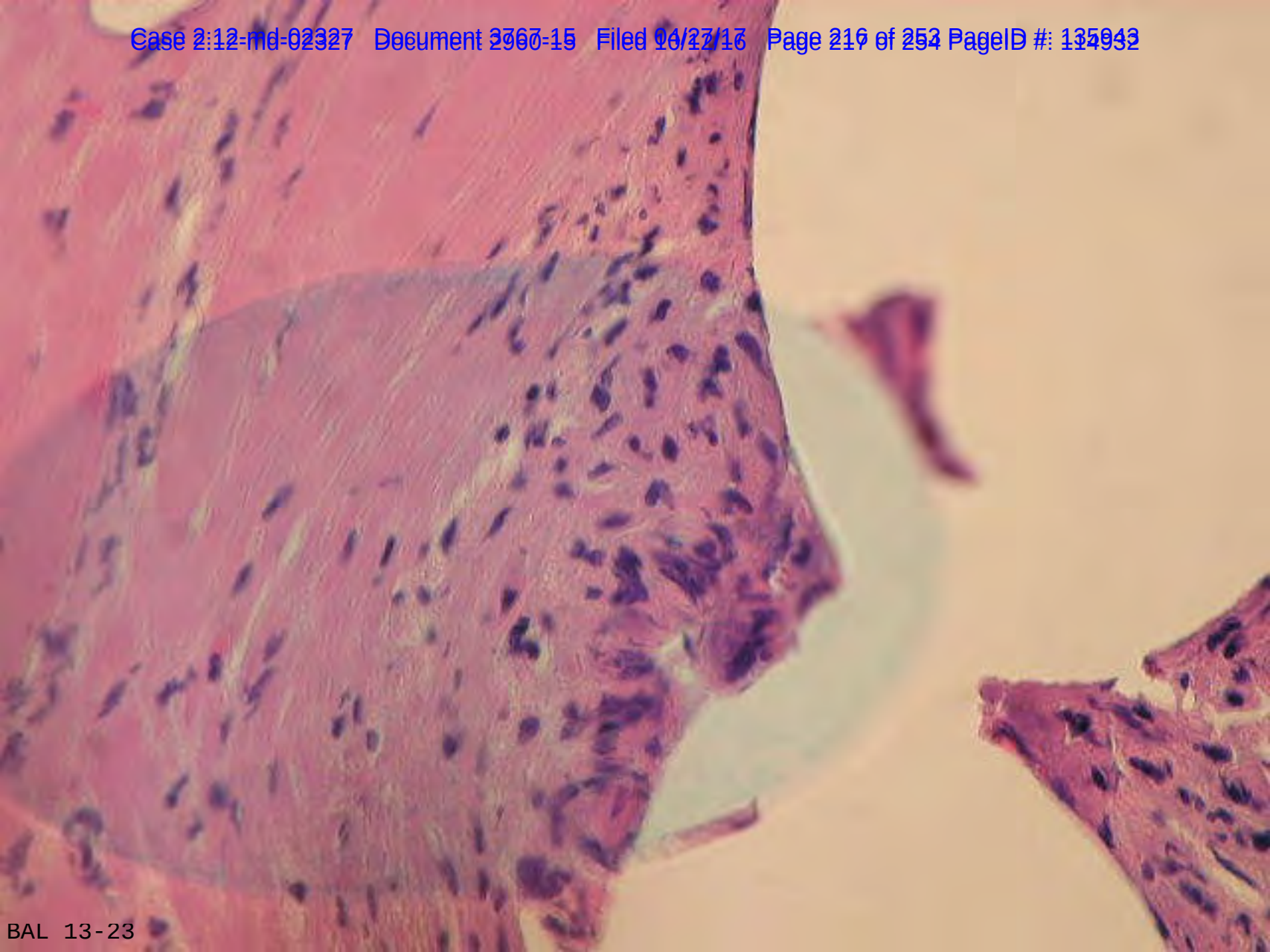


BAL 13-22

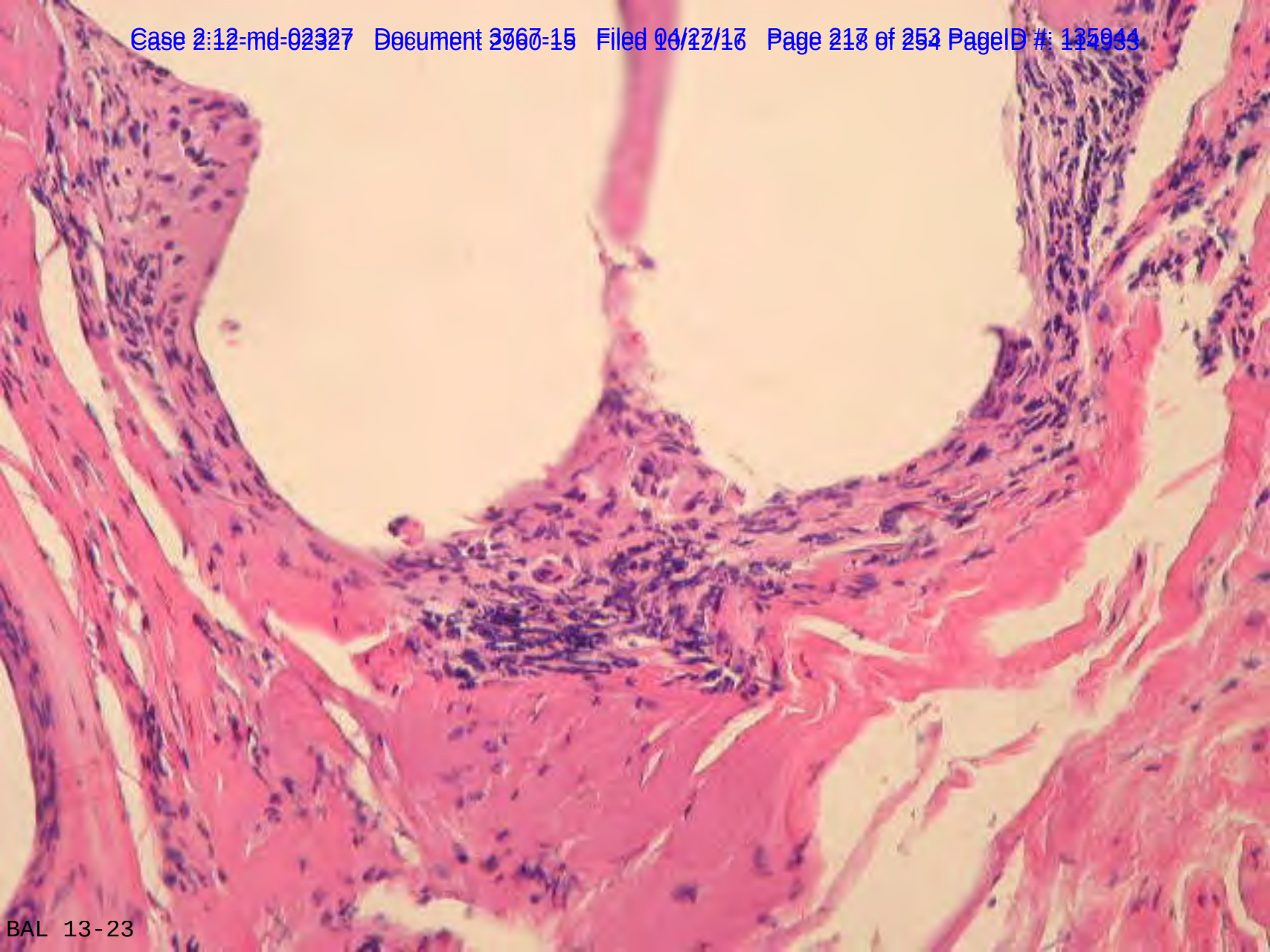


BAL 13-23

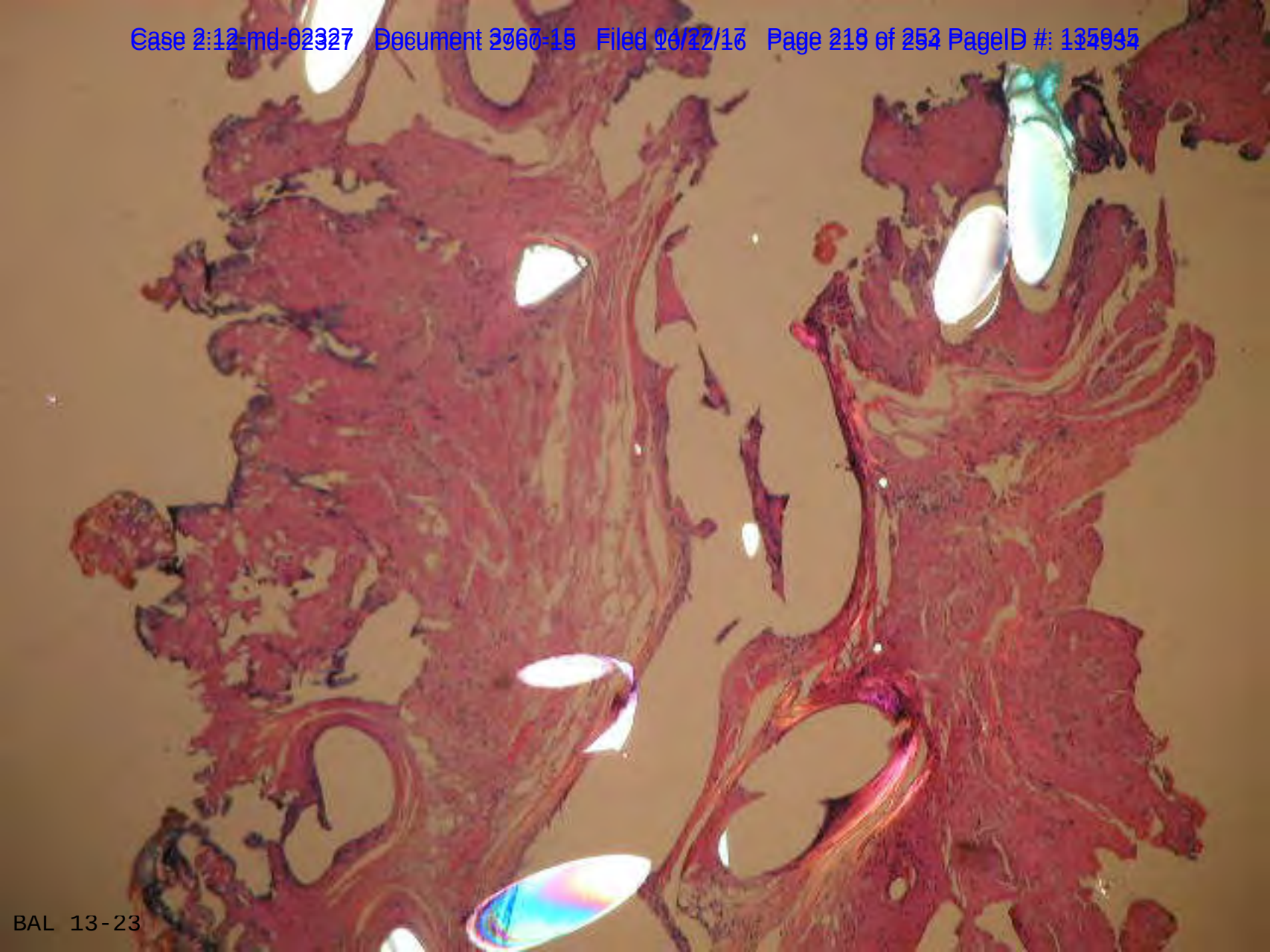

BAL 13-23
200 µm



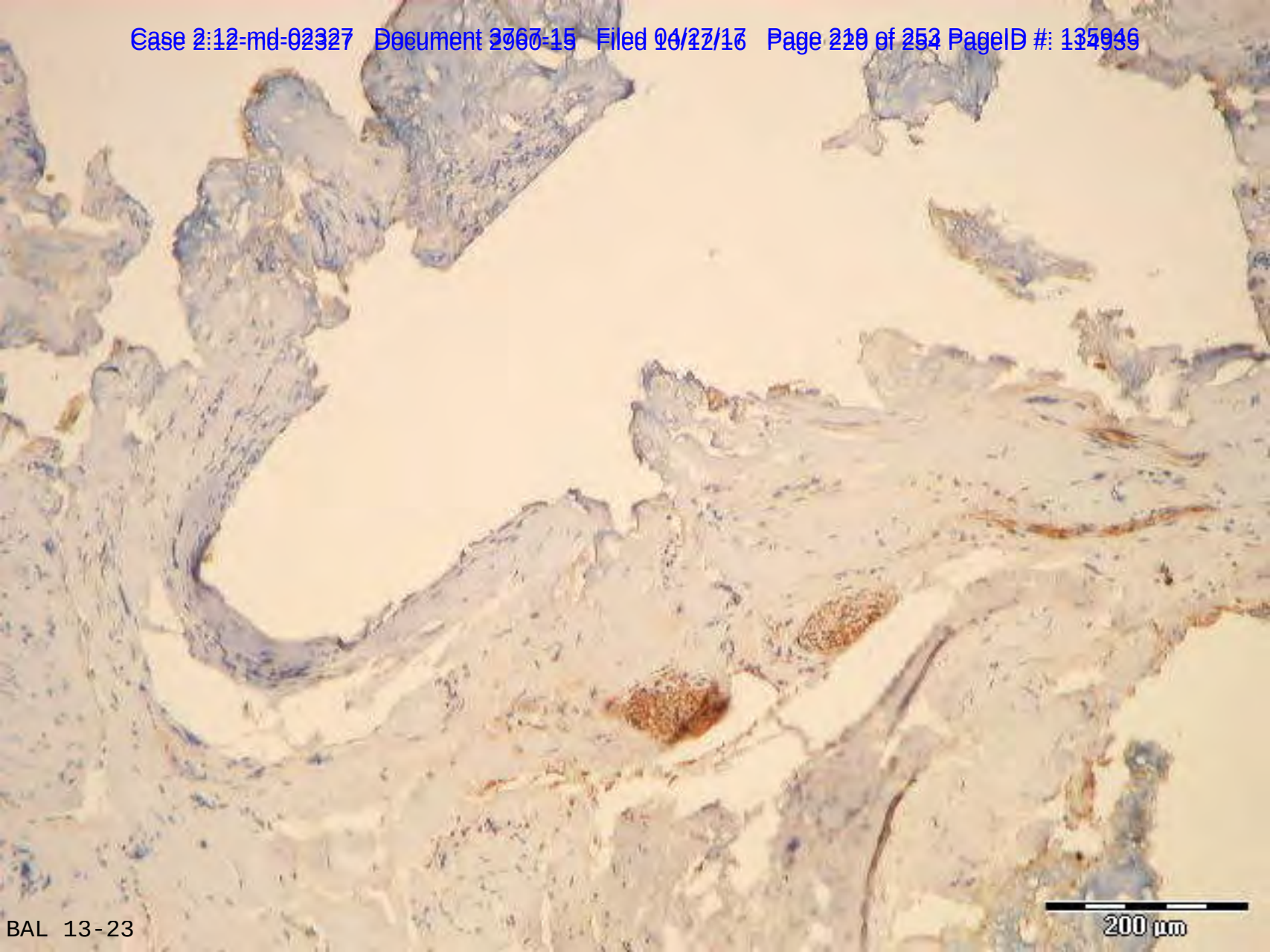
BAL 13-23

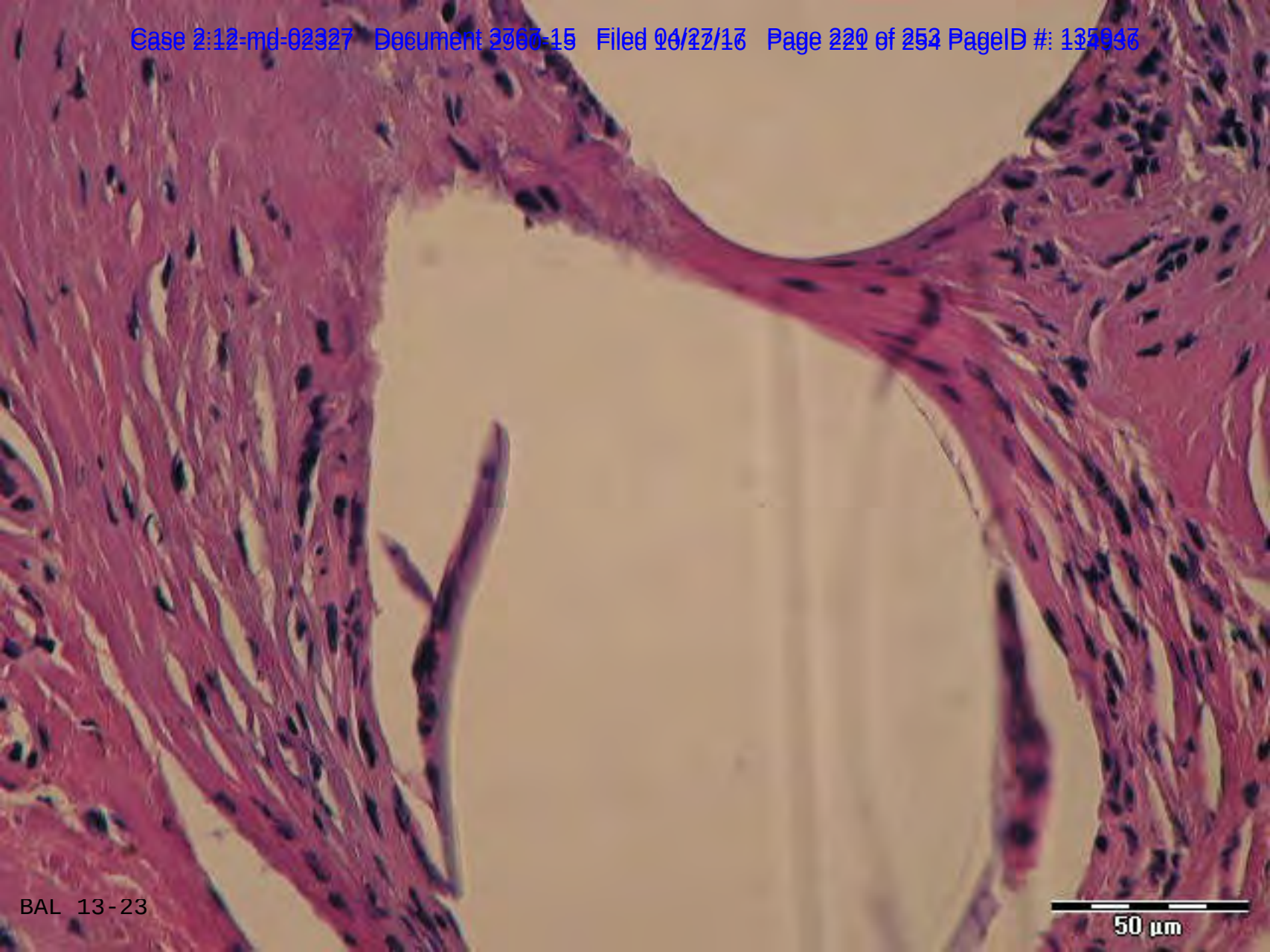


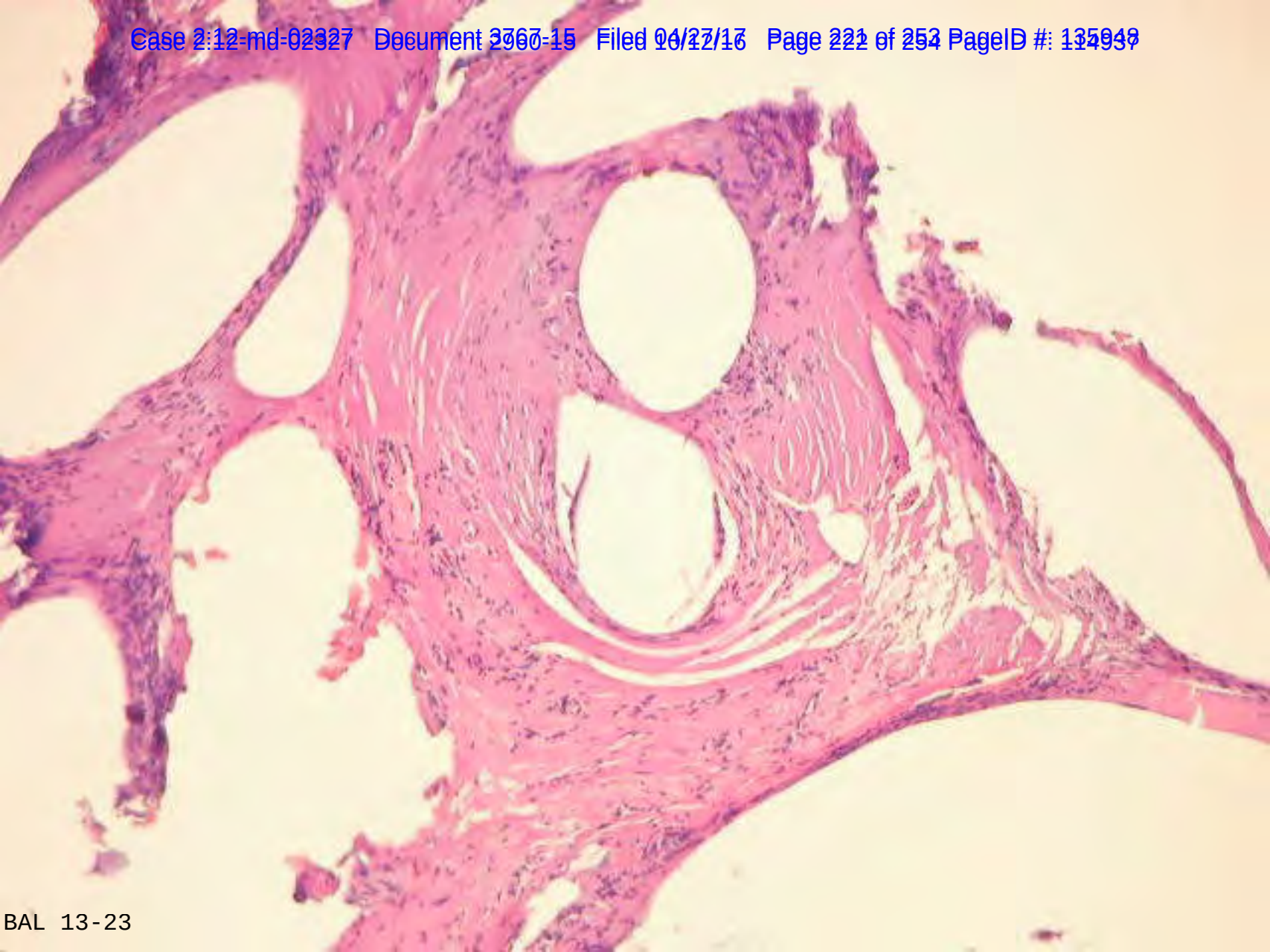
BAL 13-23



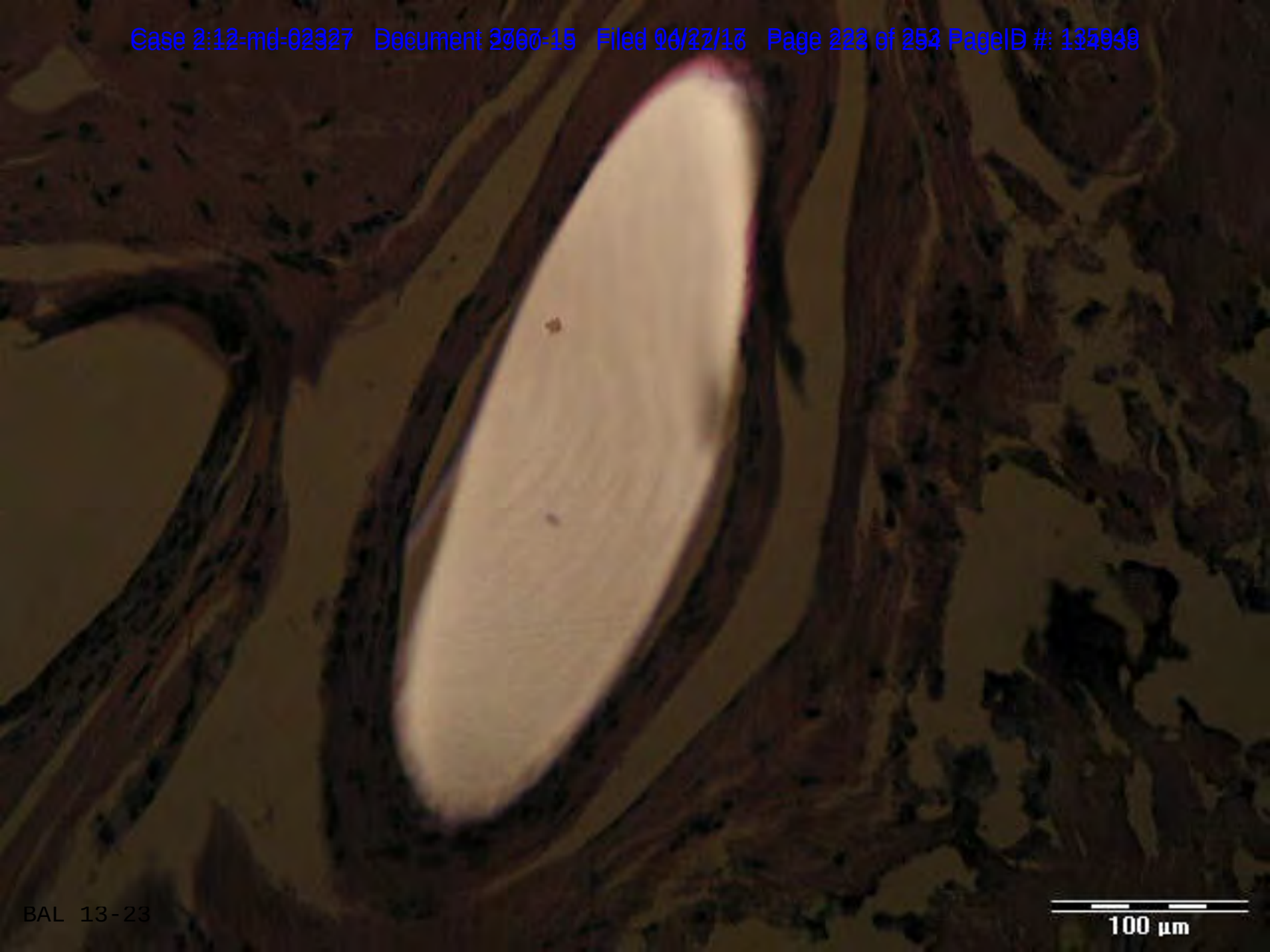
BAL 13-23

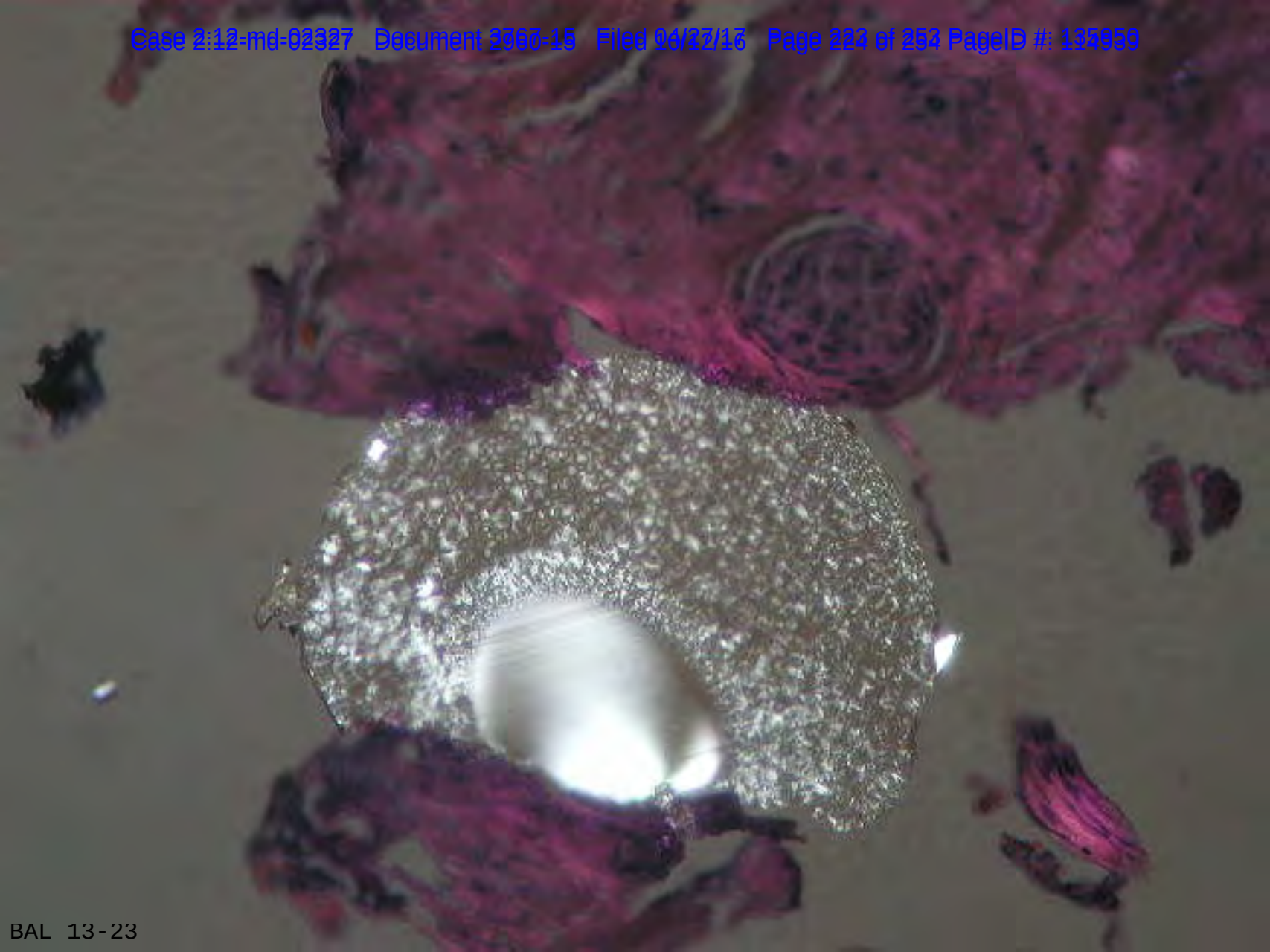

BAL 13-23
200 µm


BAL 13-23
50 µm



BAL 13-23


BAL 13-23
100 µm



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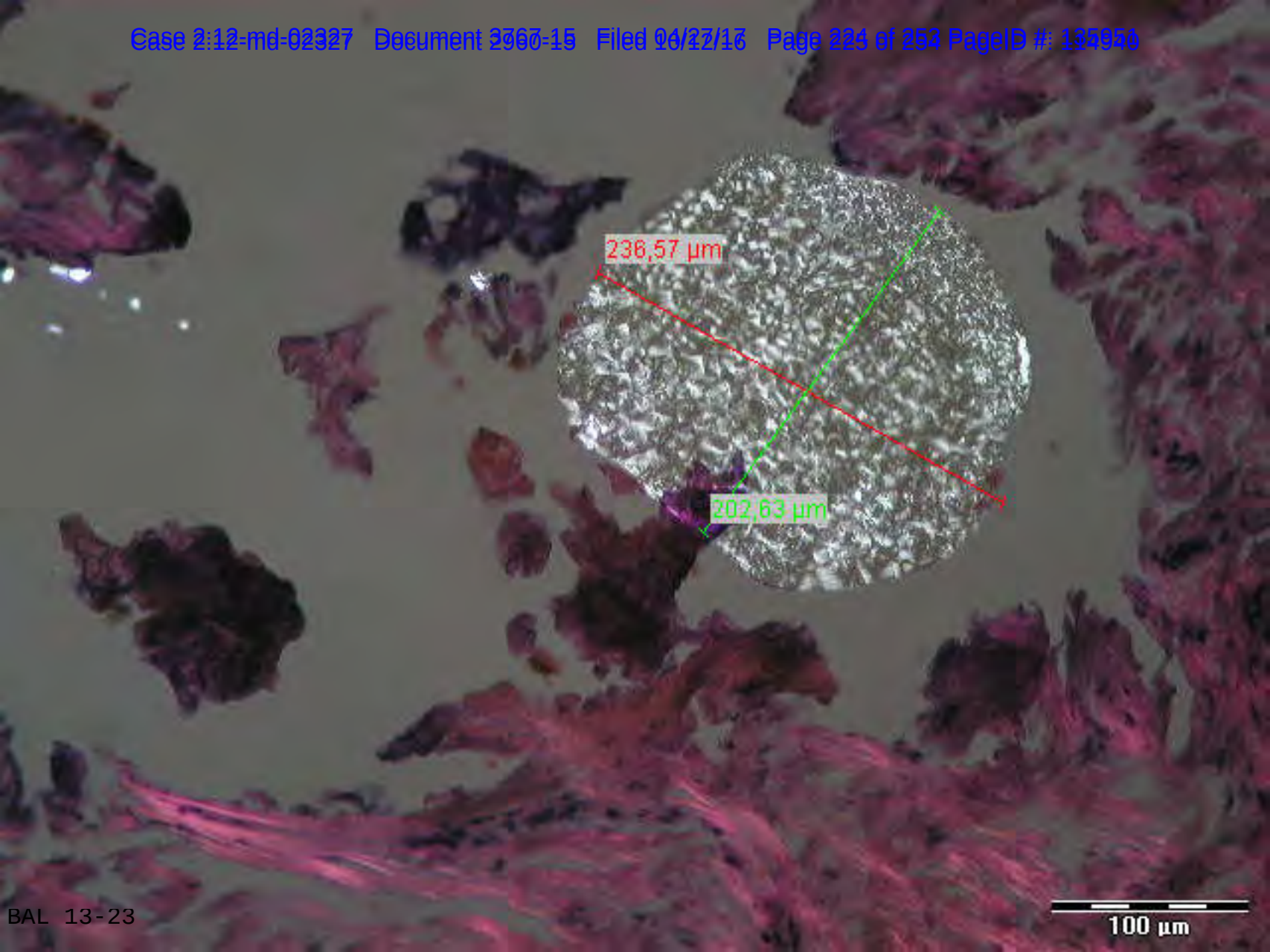
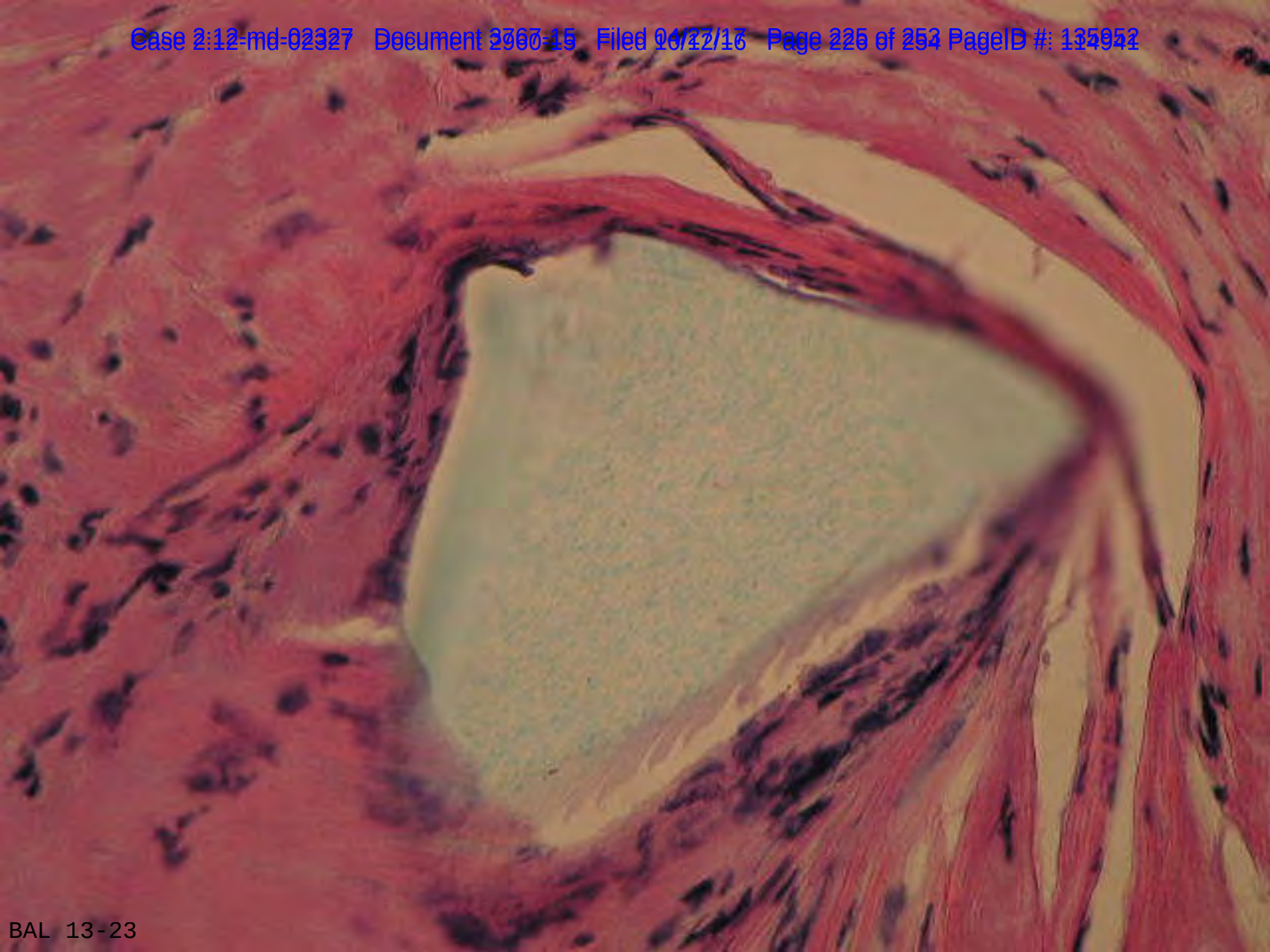

236,57 µm
202,63 µm
BAL 13-23
100 µm



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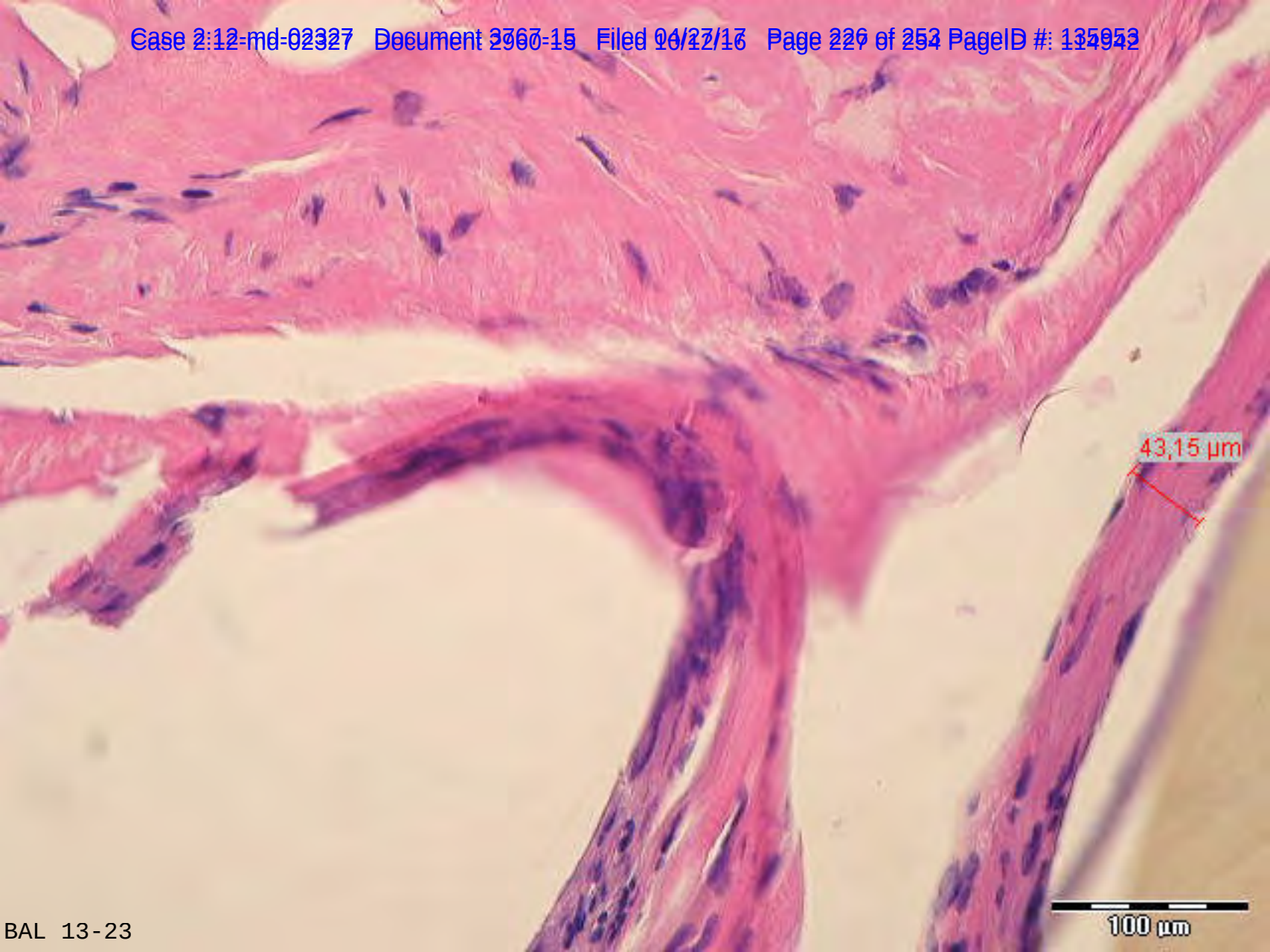
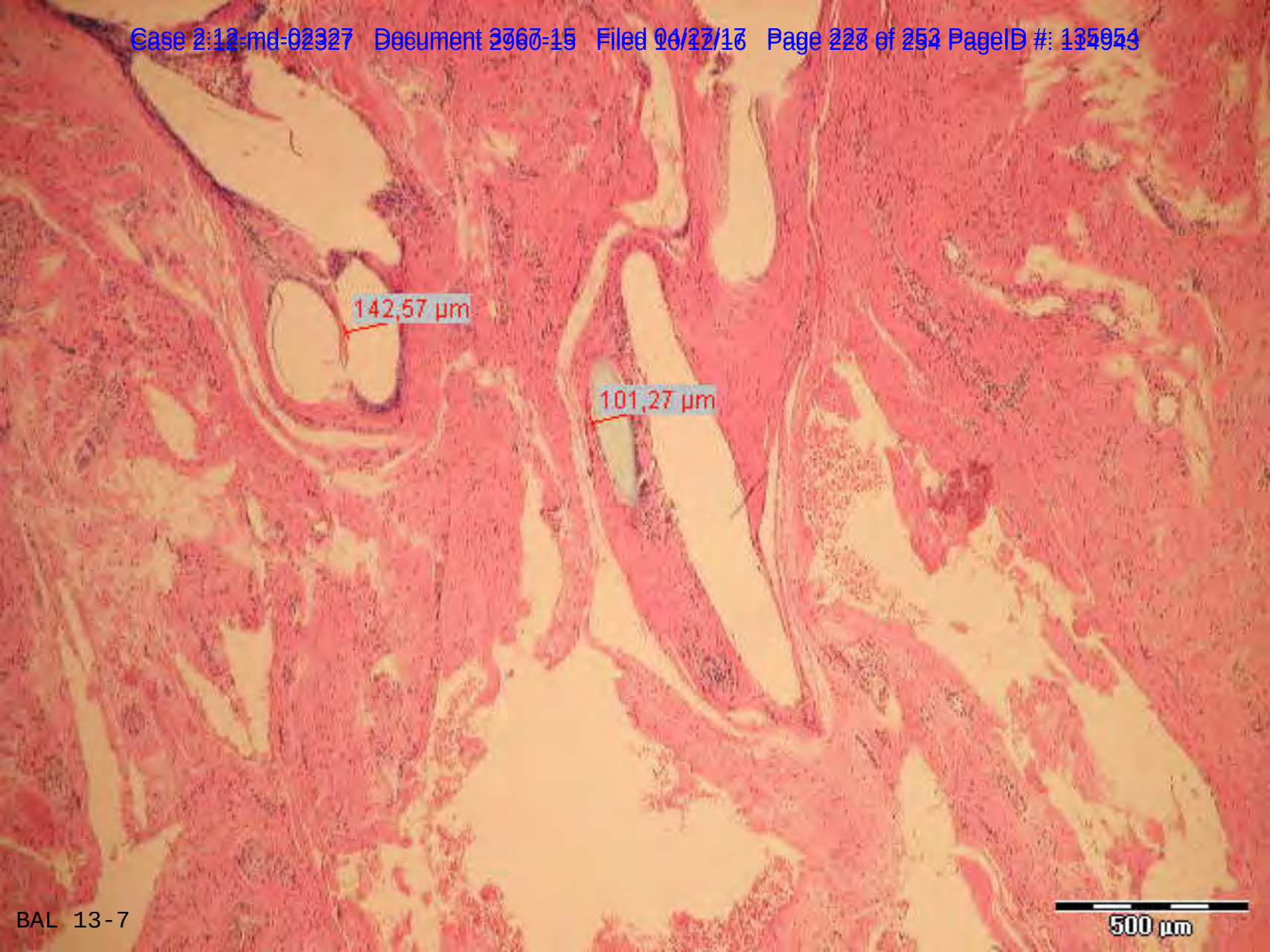
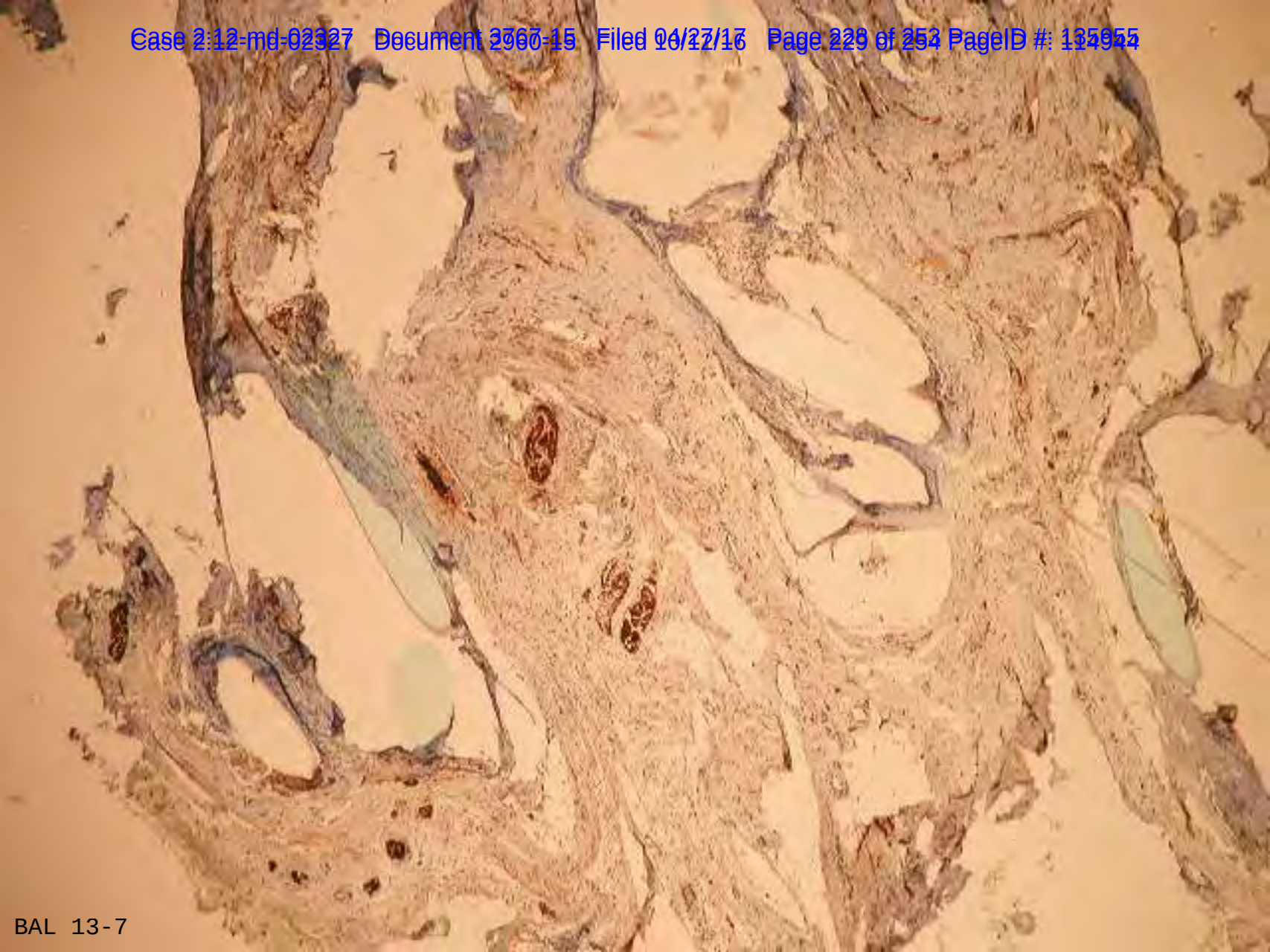


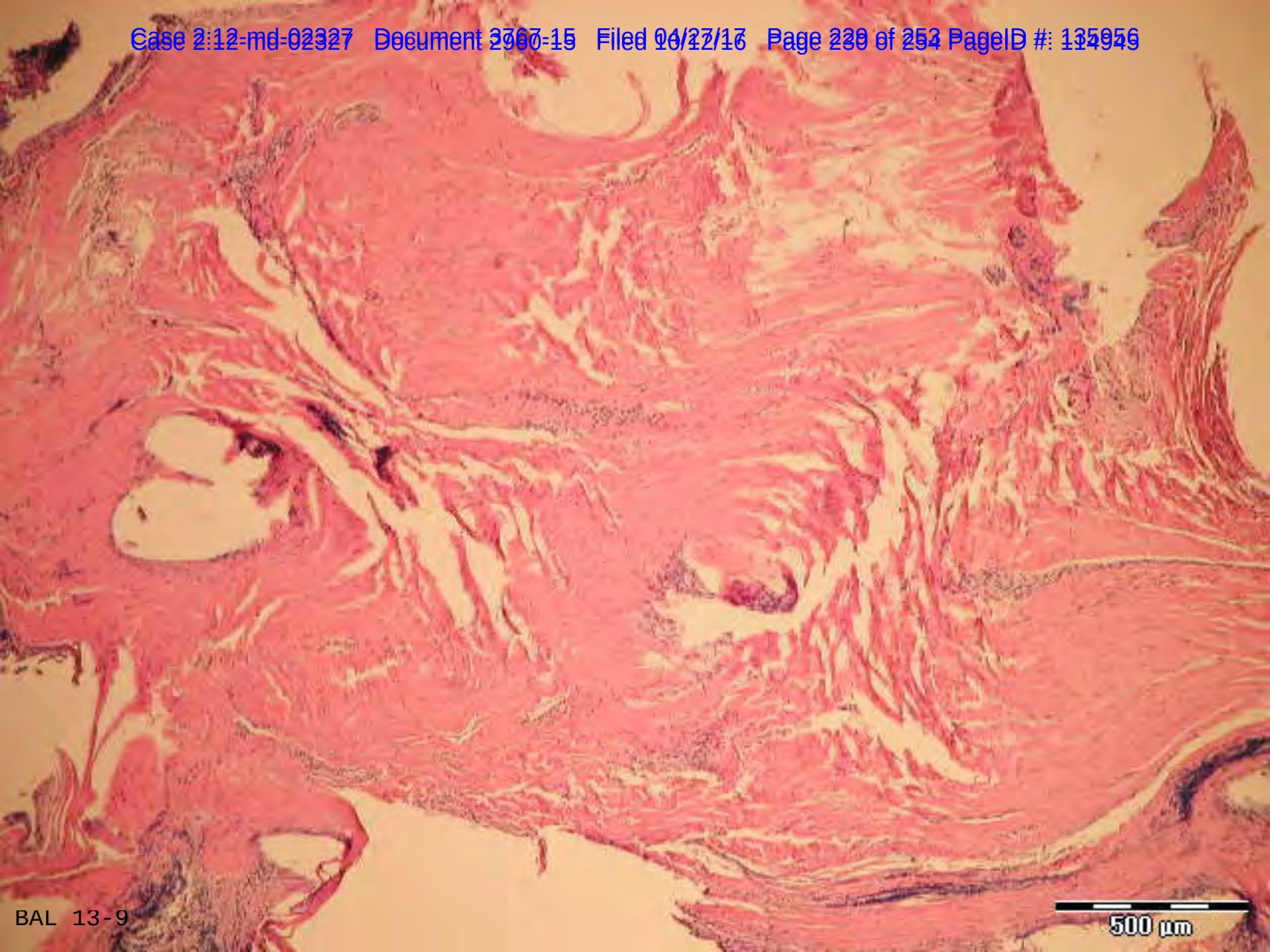
BAL 13-23

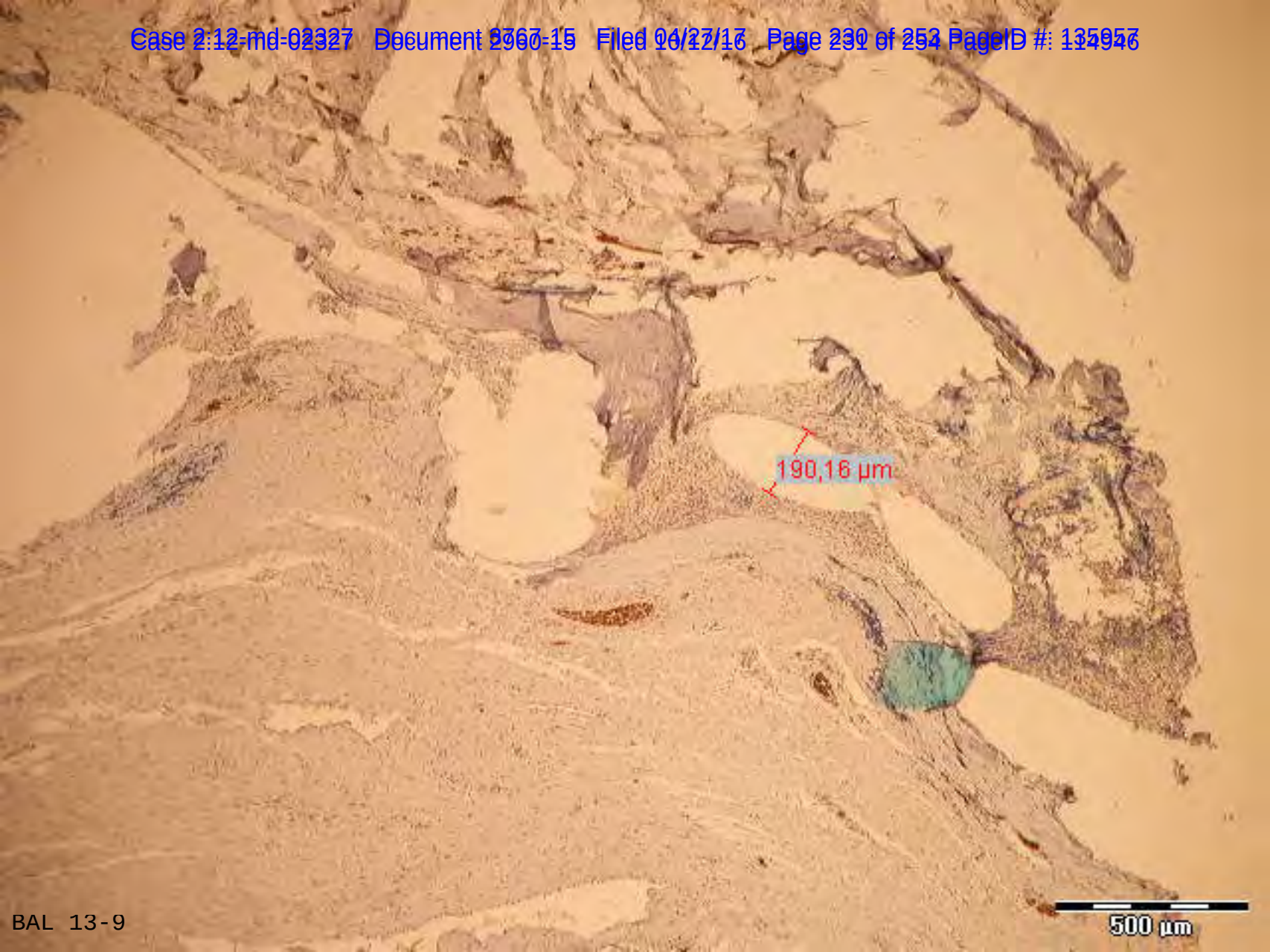


BAL 13-7

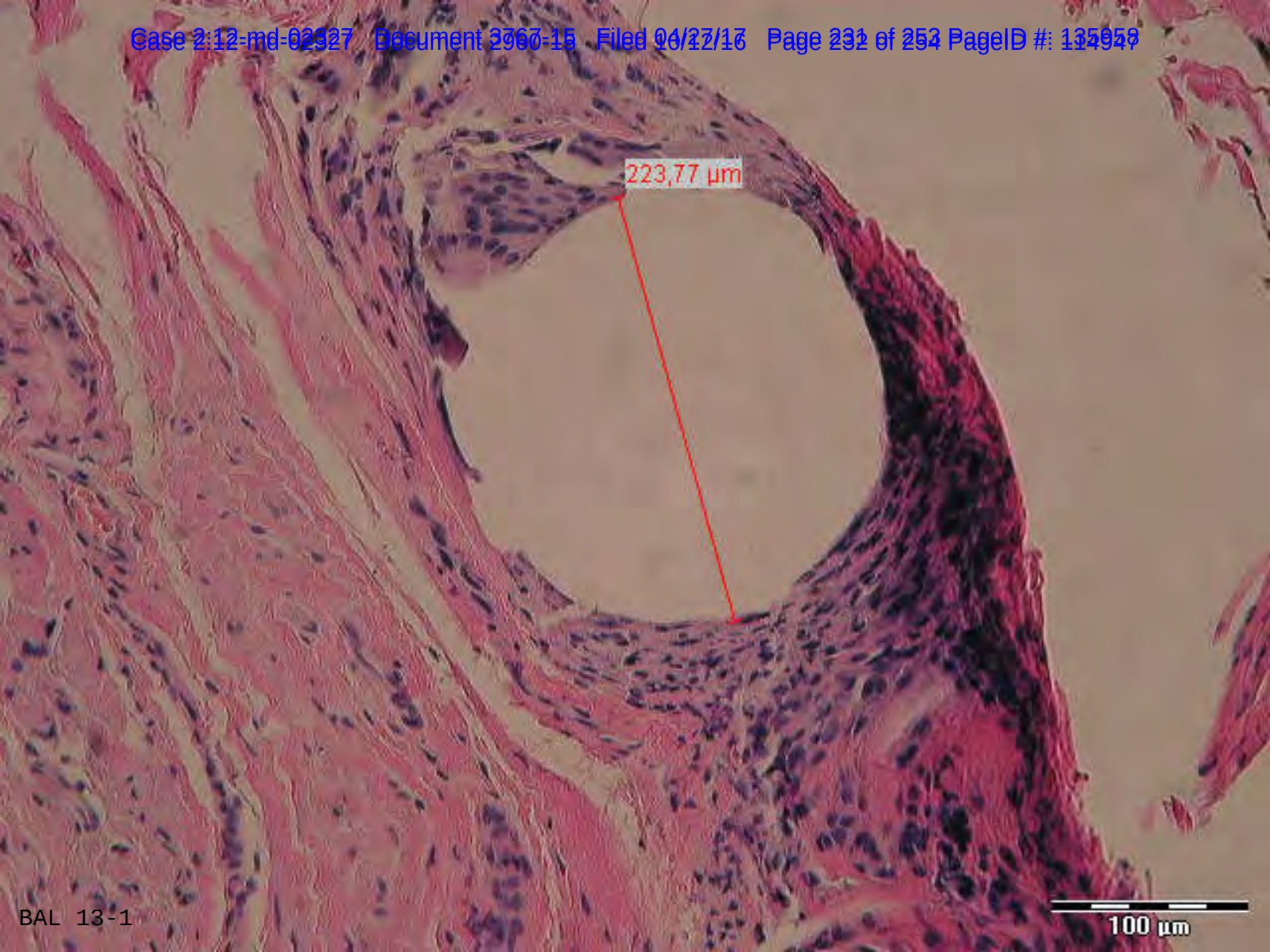


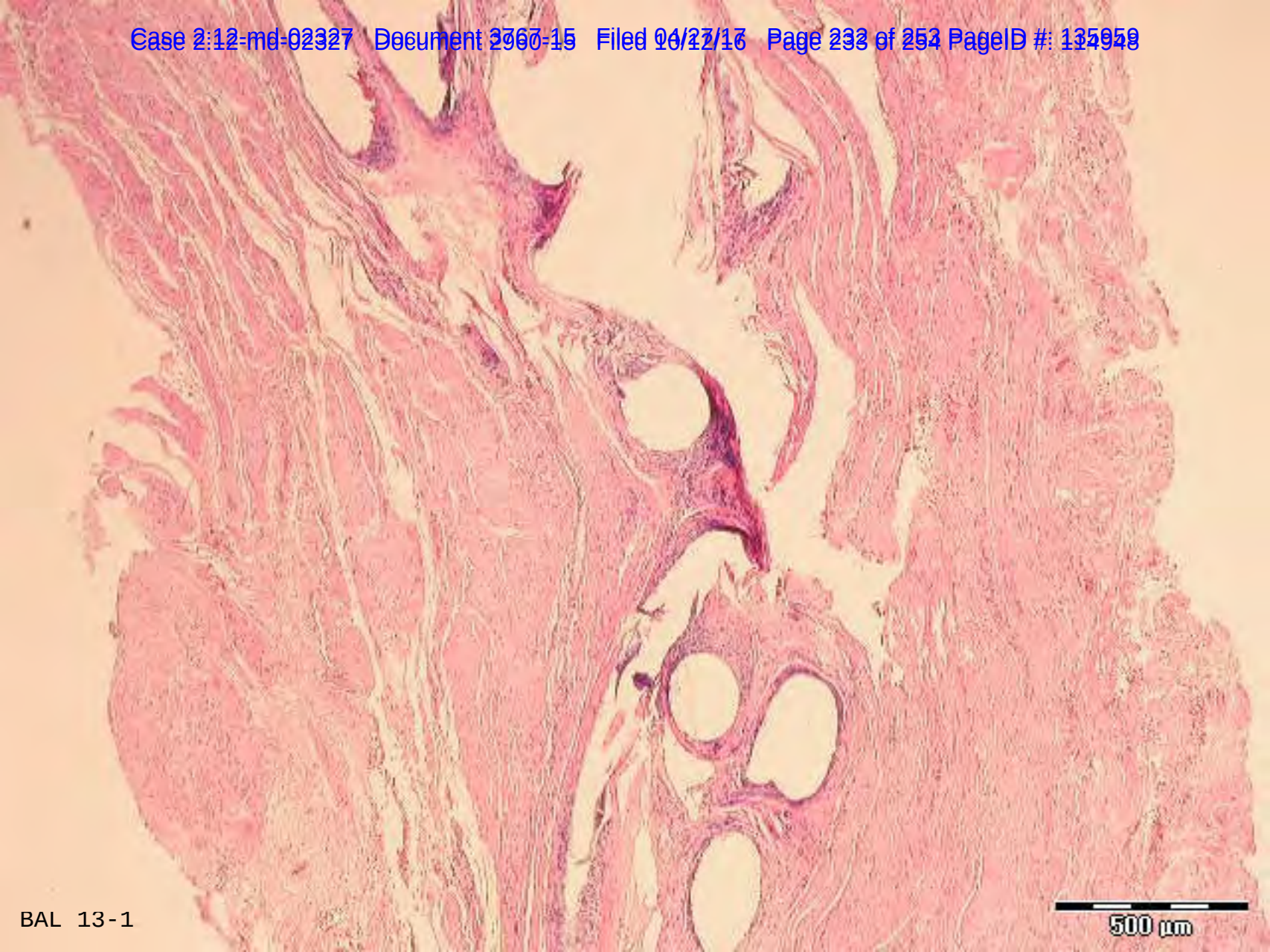
BAL 13-7

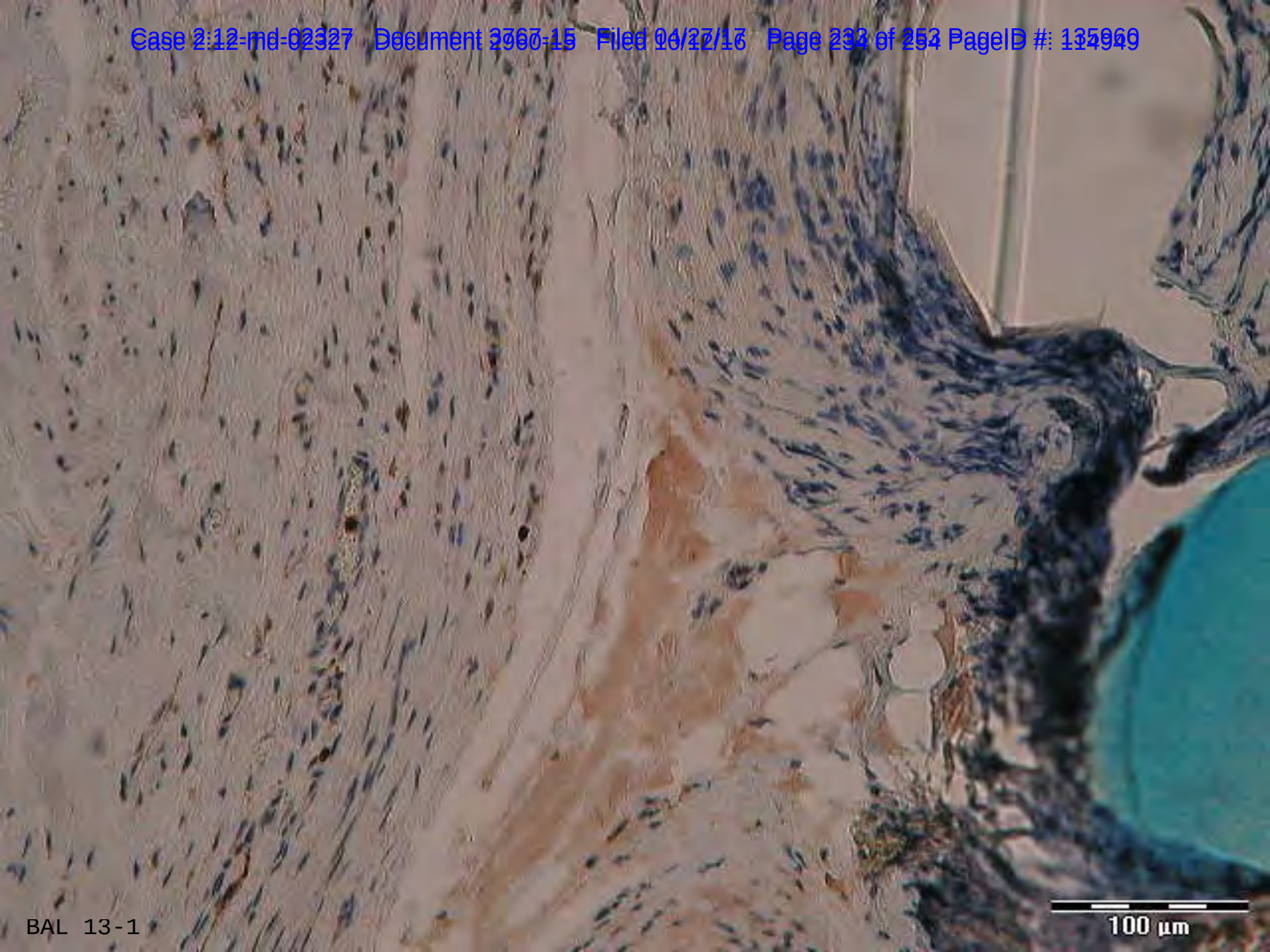

BAL 13-9
500 µm

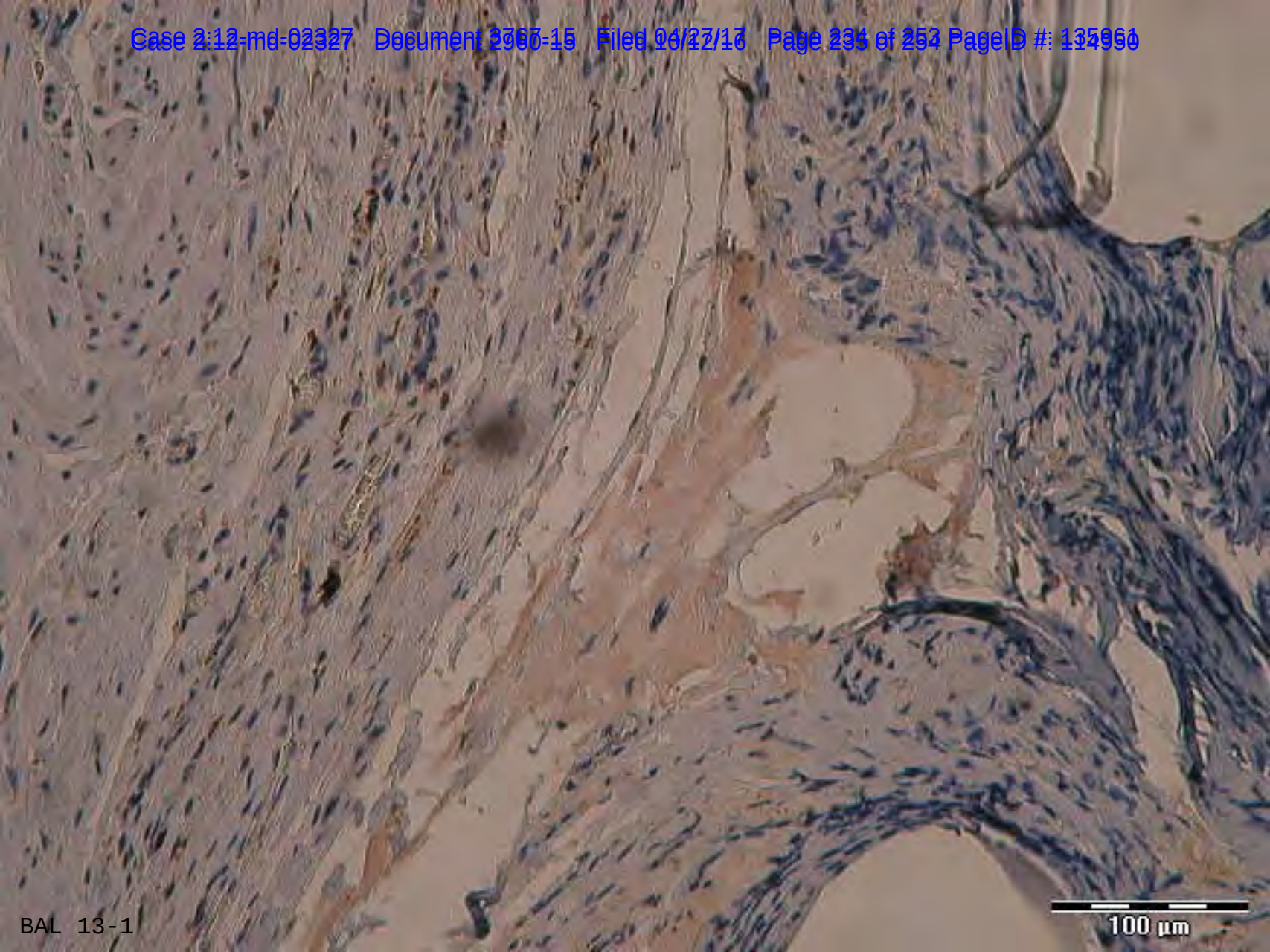


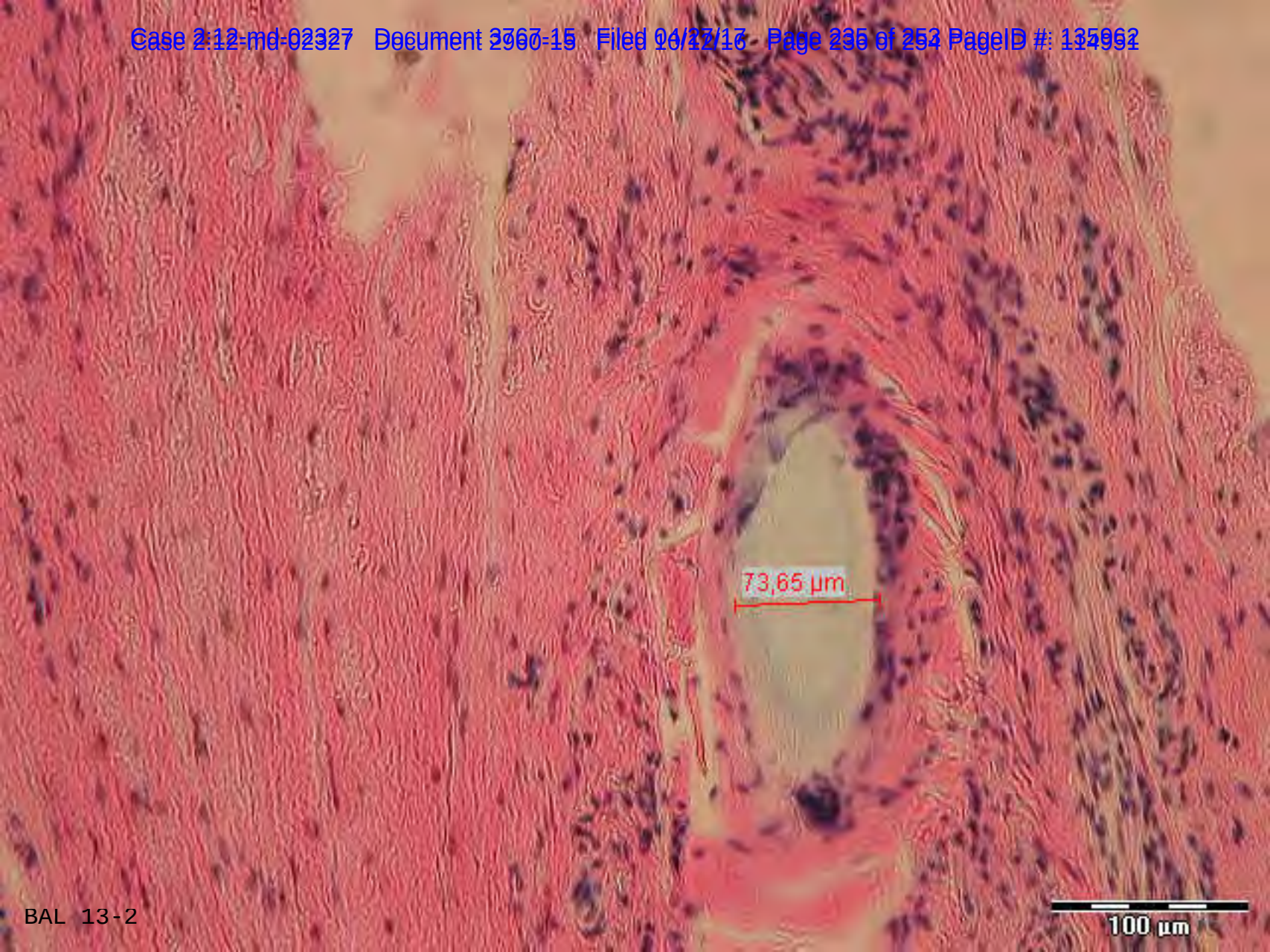
BAL 13-9

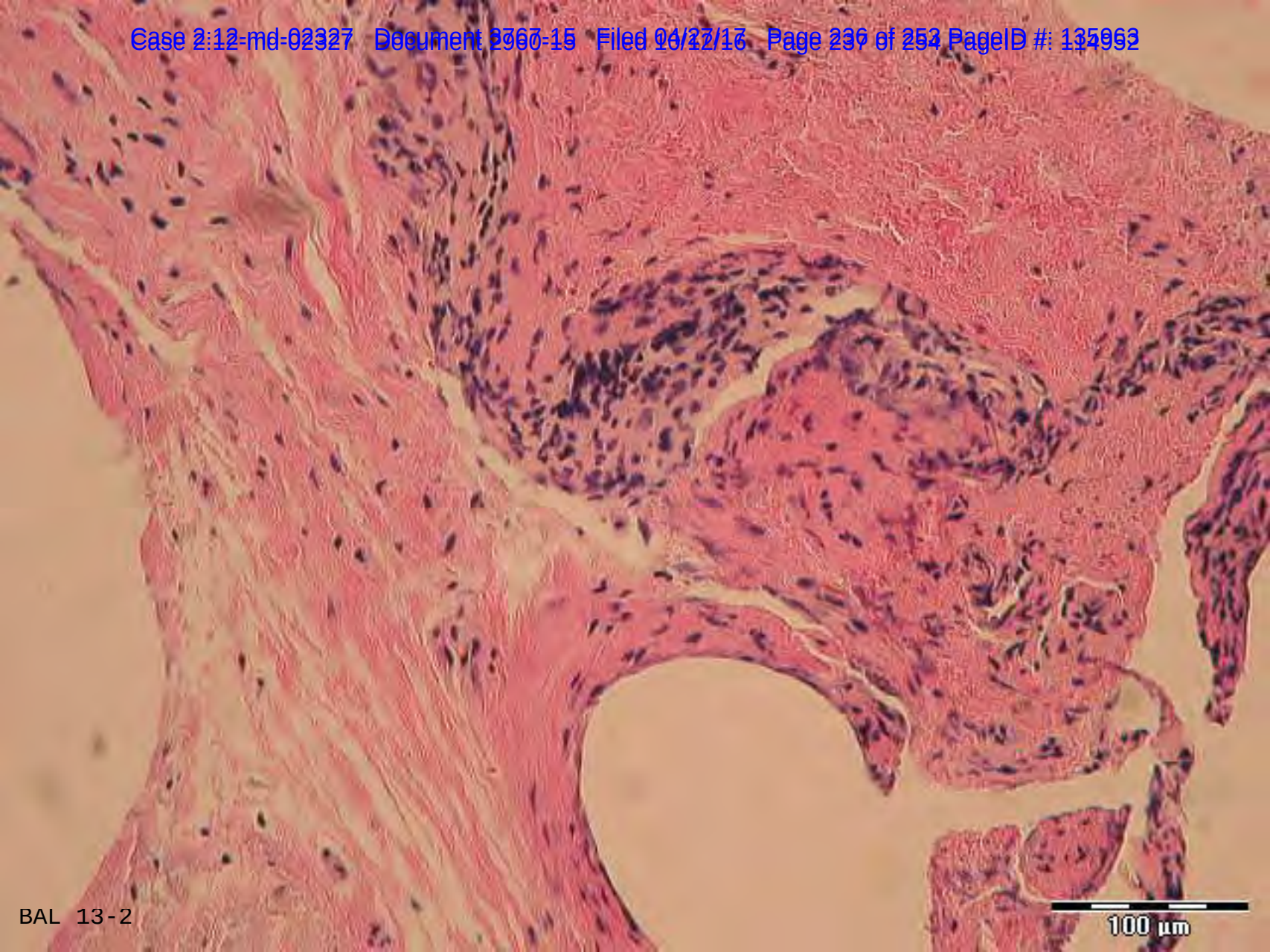

223,77 µm
BAL 13-1
100 µm

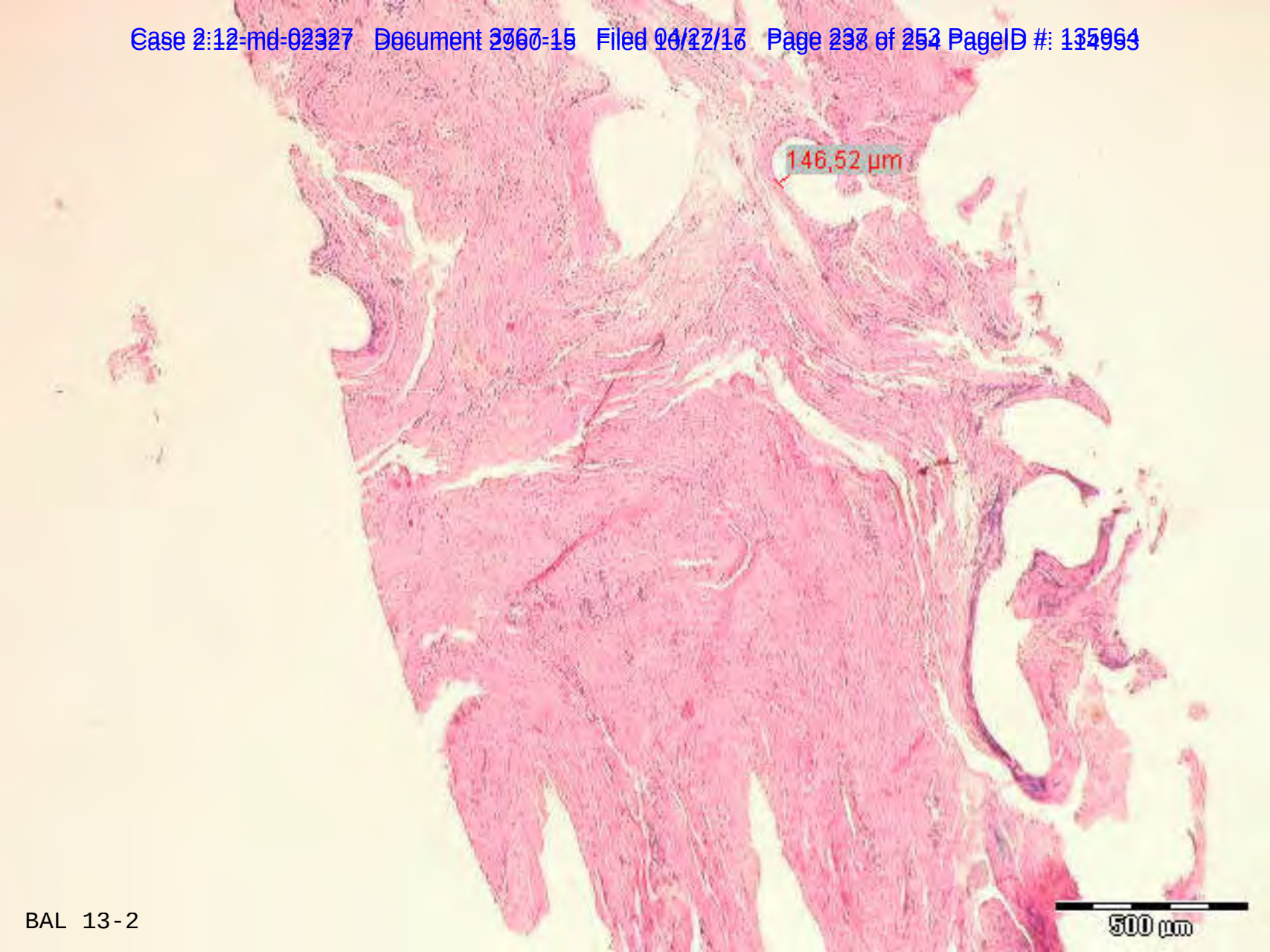

BAL 13-1
500 µm


BAL 13-1
100 µm

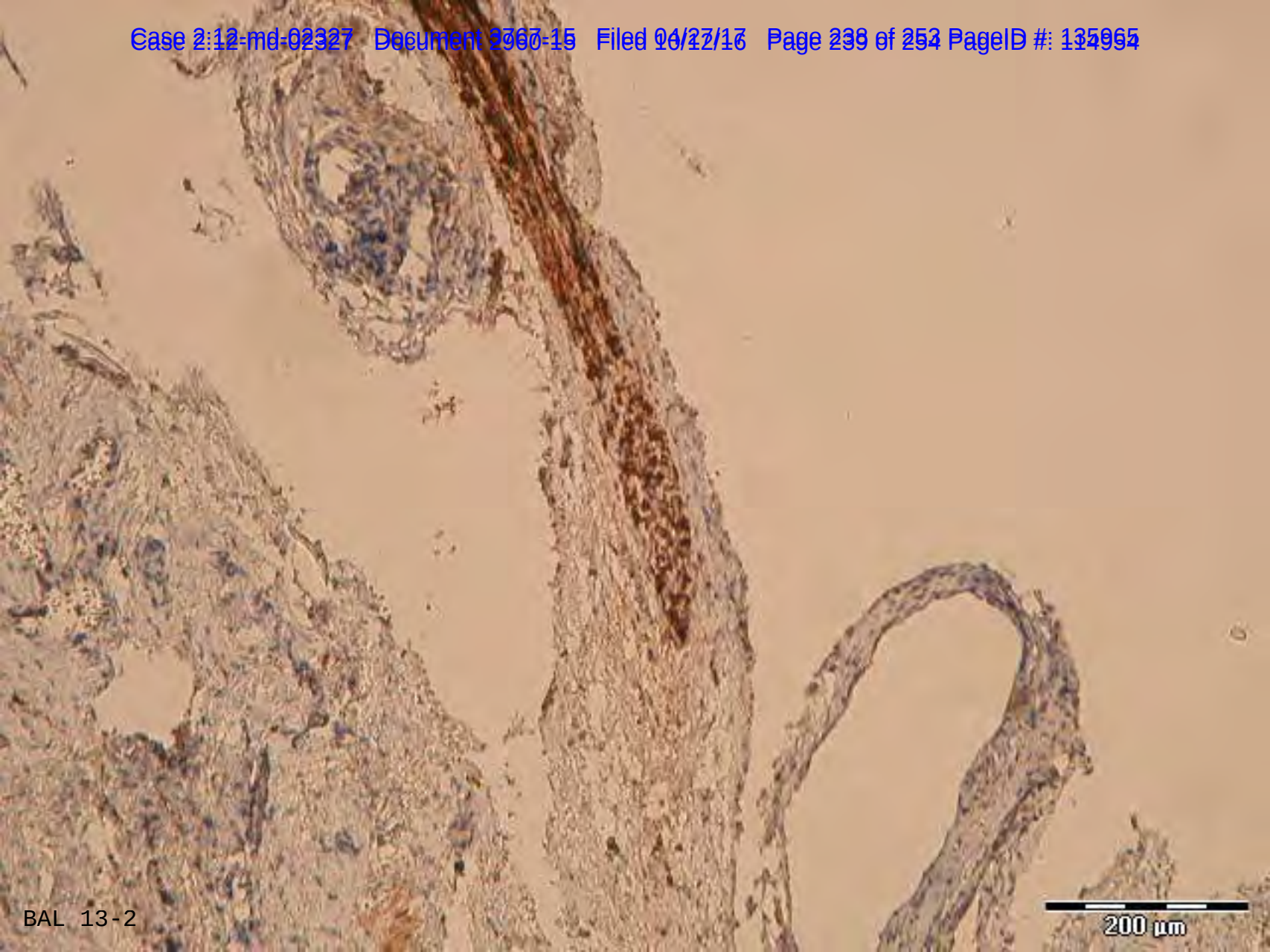

BAL 13-1
100 µm

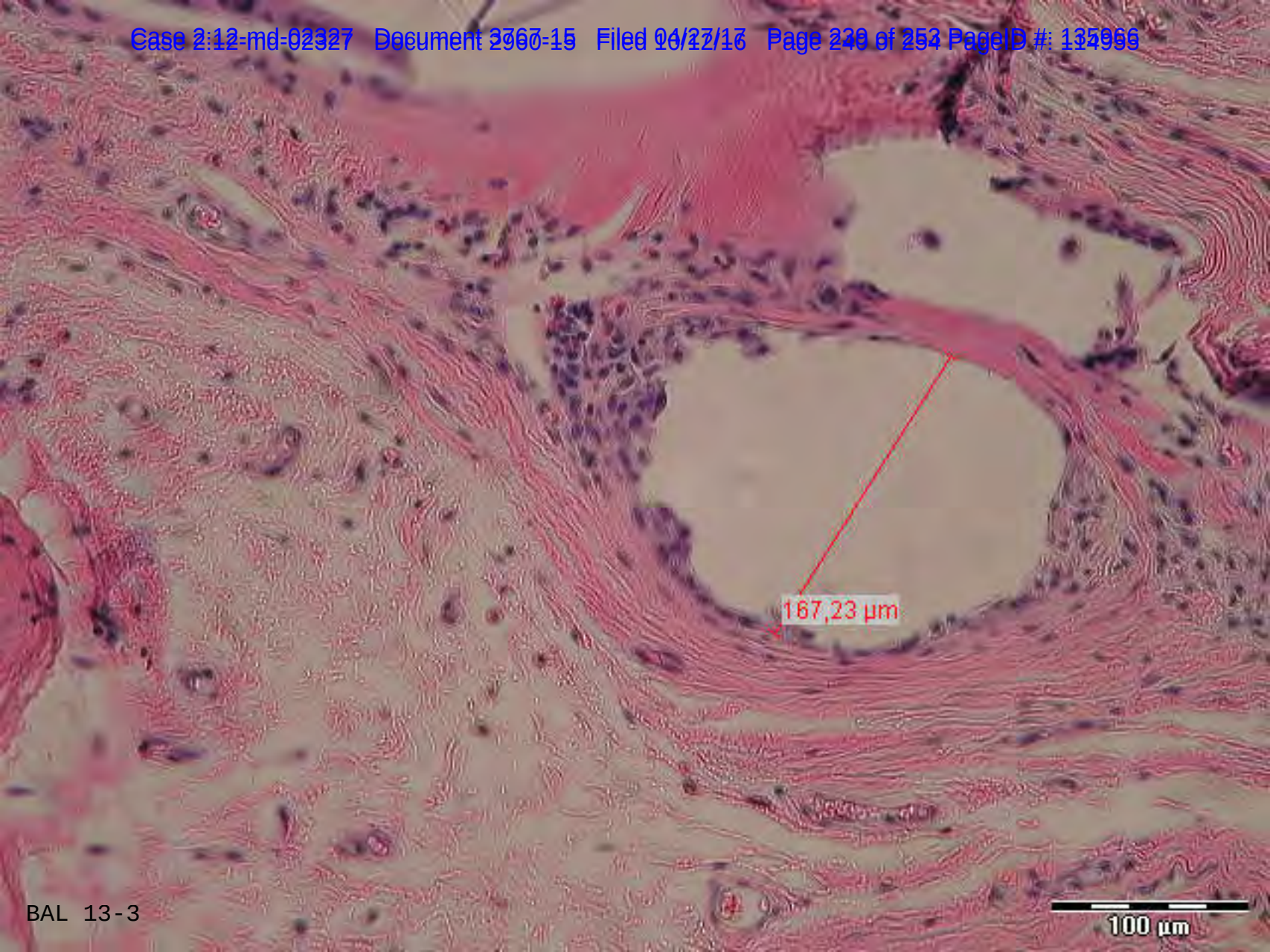

73,65 µm
BAL 13-2
100 µm

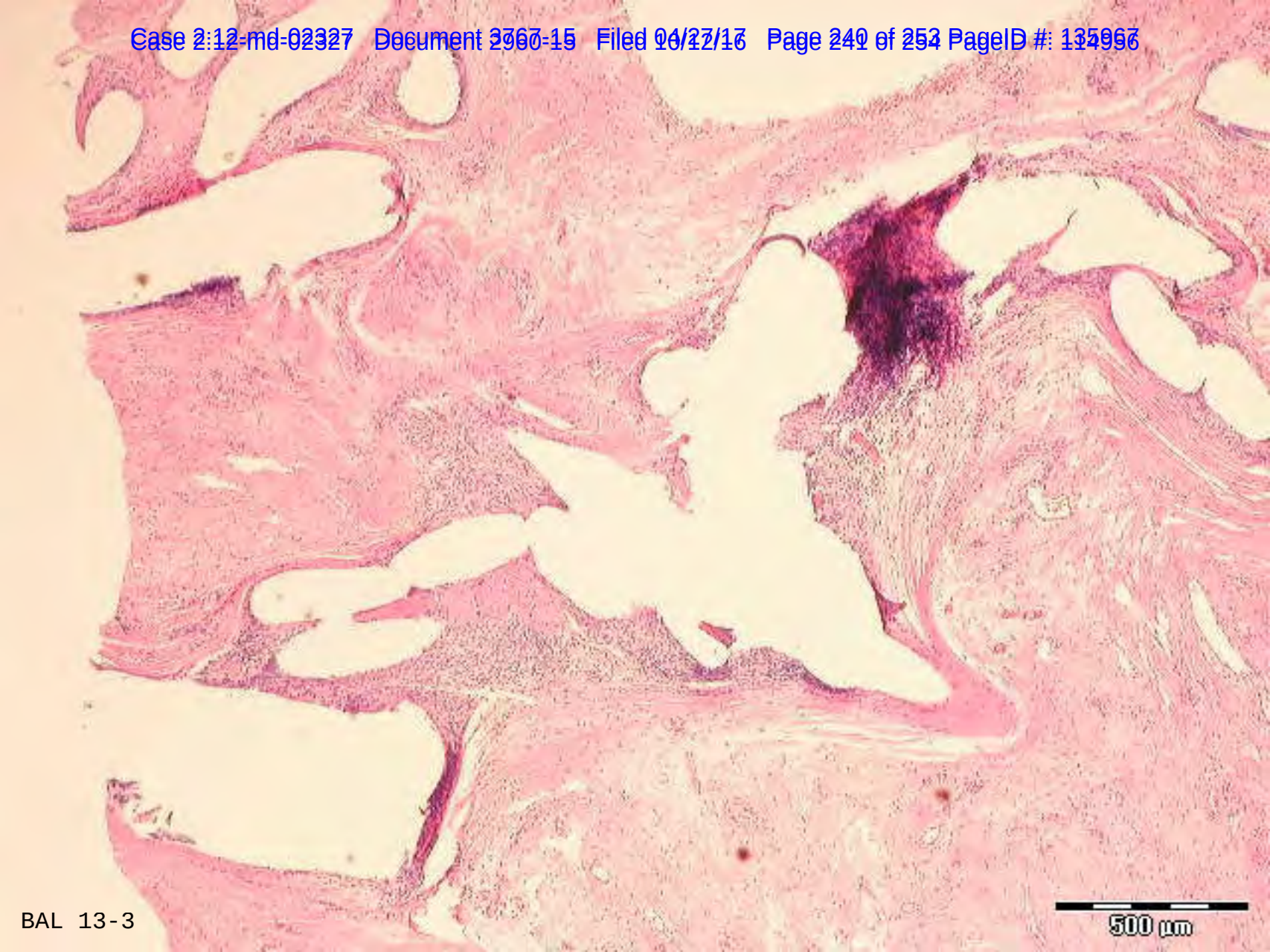

BAL 13-2
100 µm

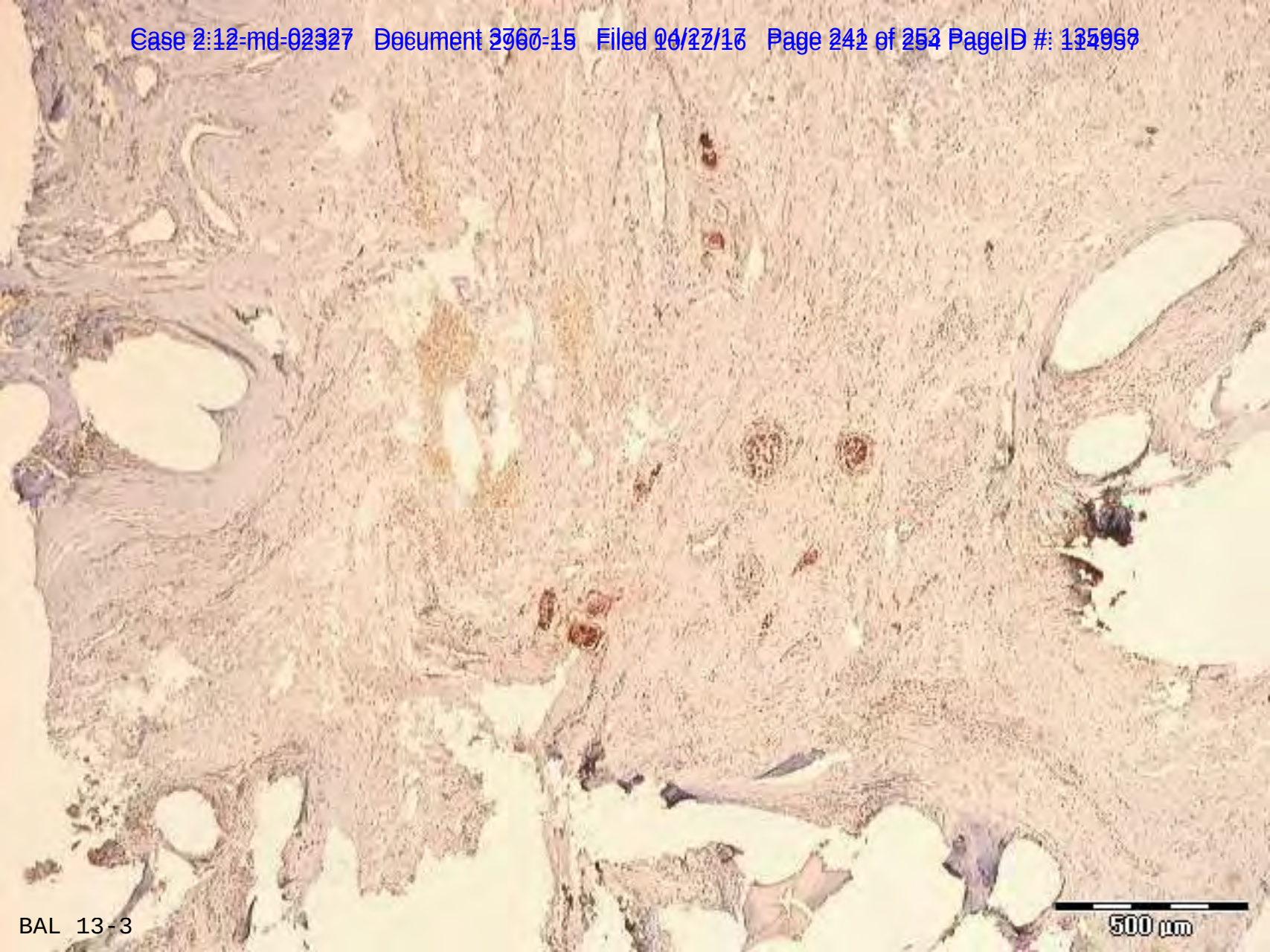


BAL 13-2

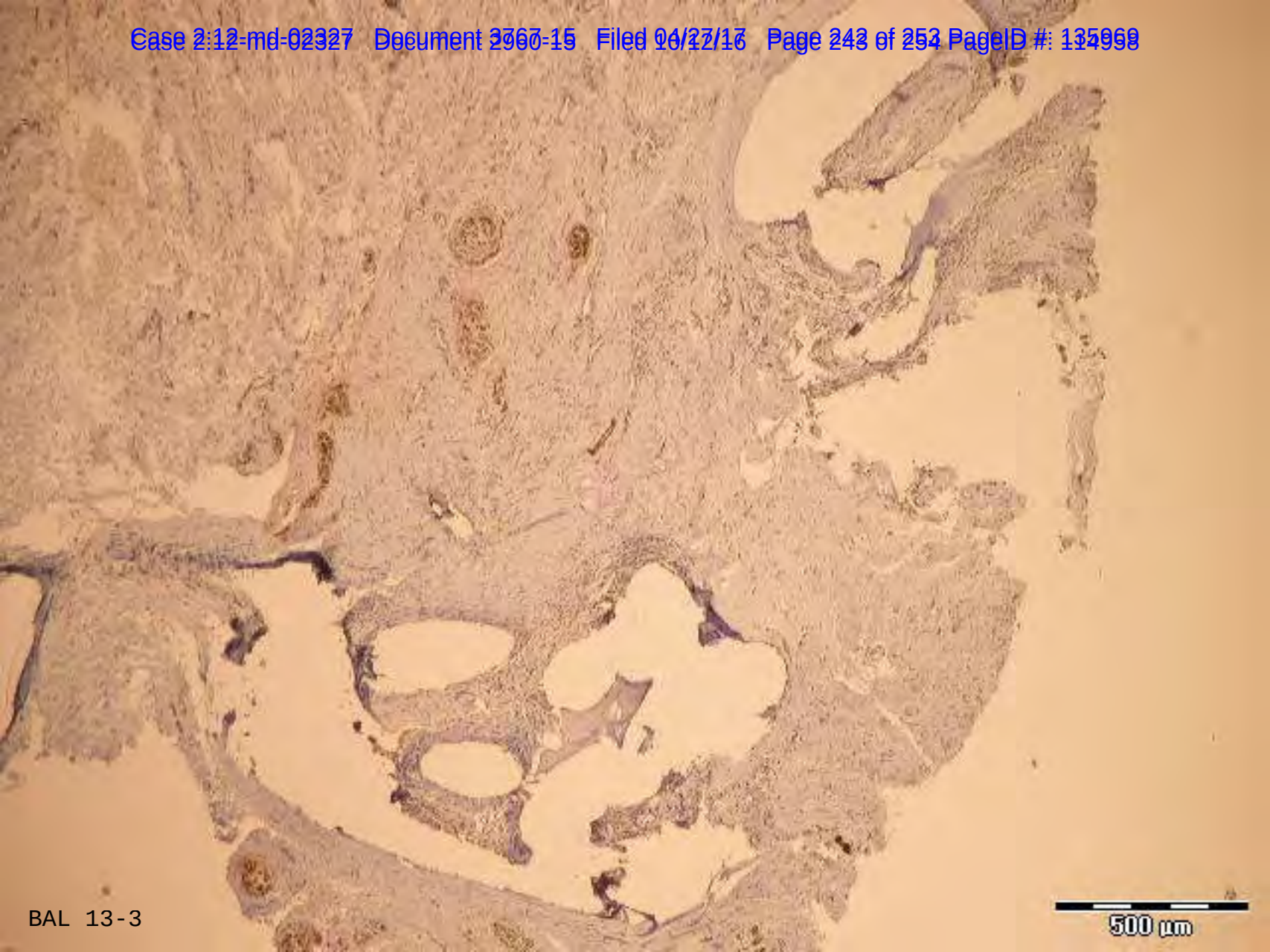

BAL 13-2
200 µm

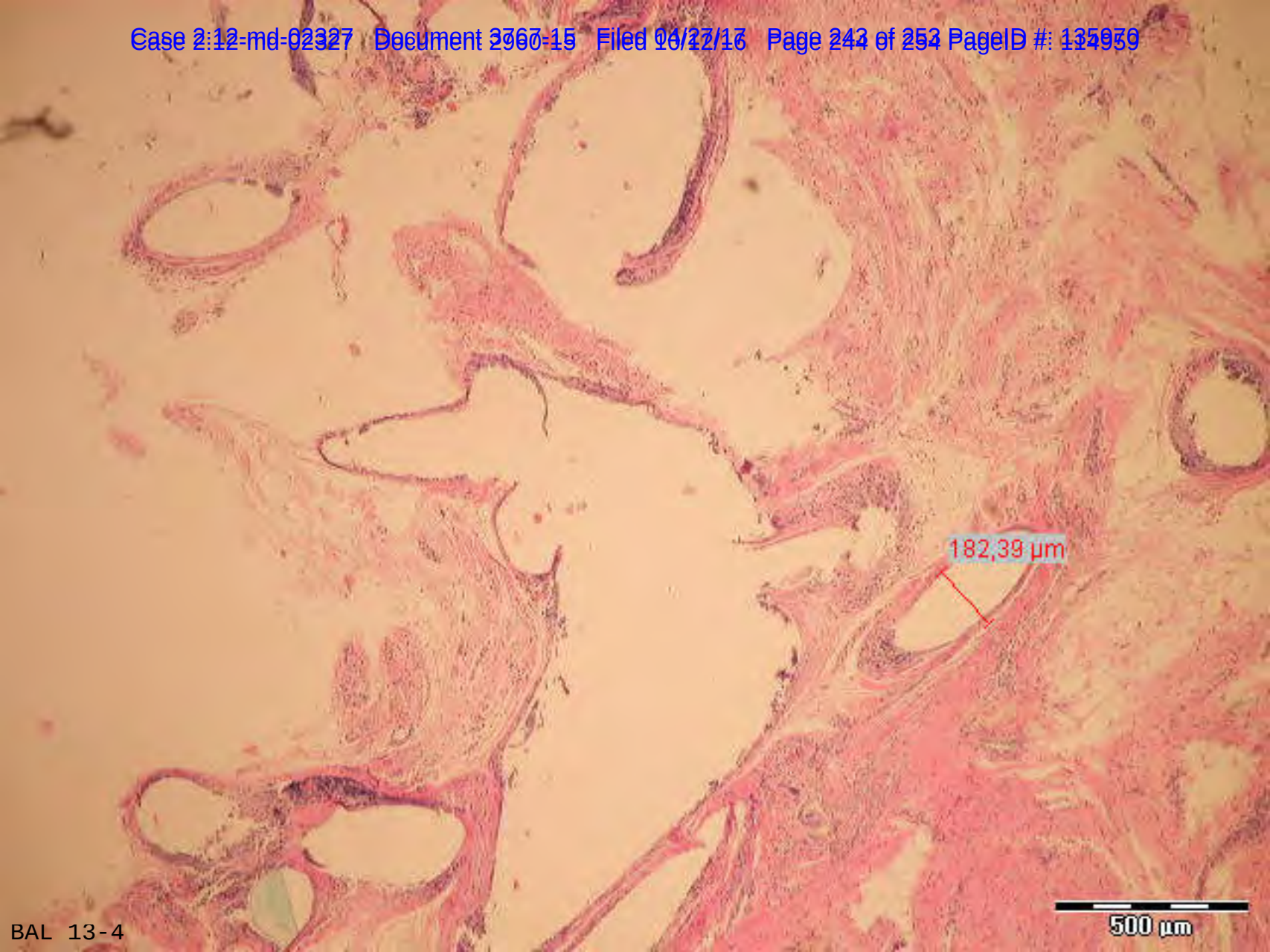

167,23 µm
BAL 13-3
100 µm

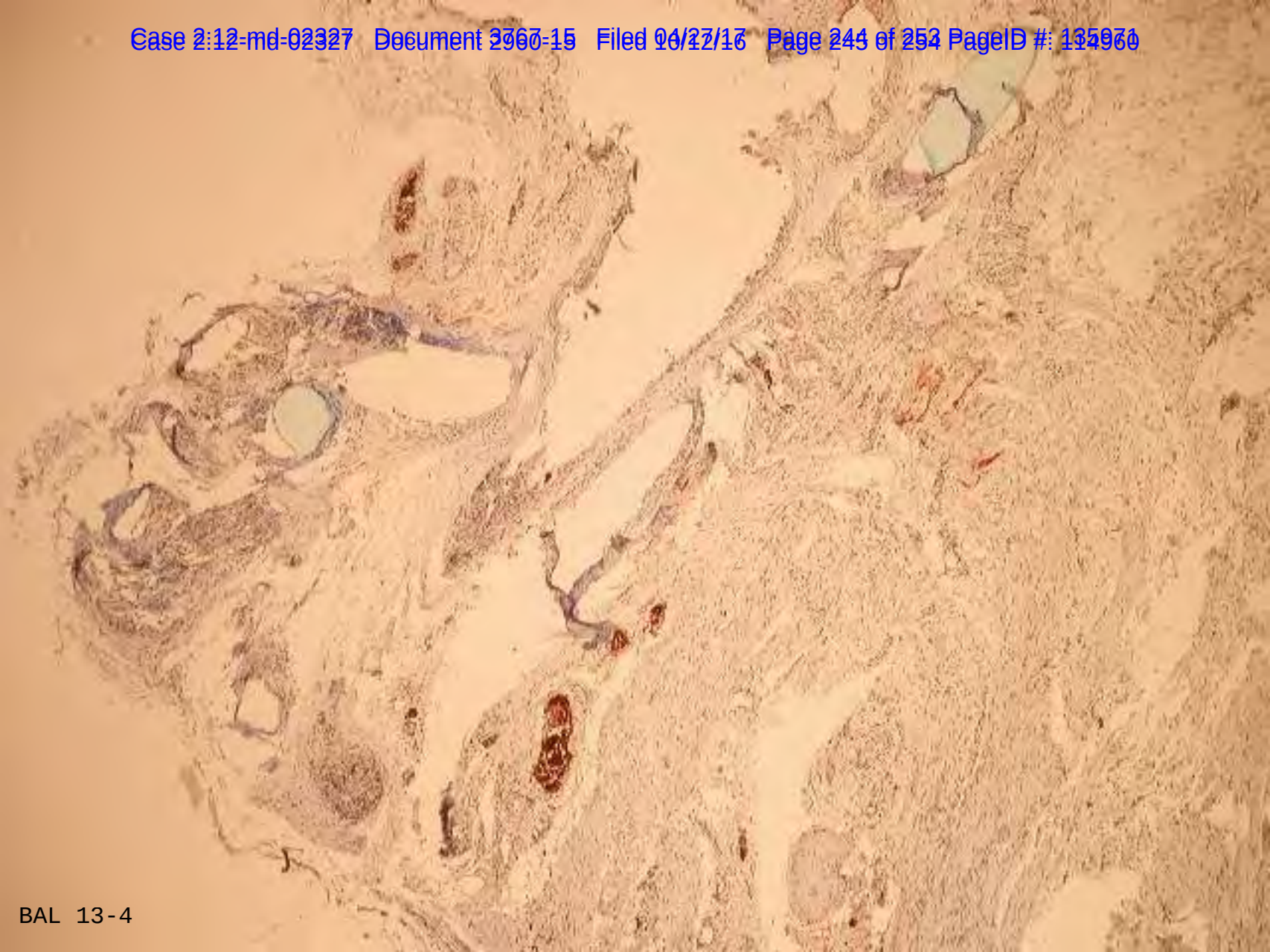

BAL 13-3
500 µm



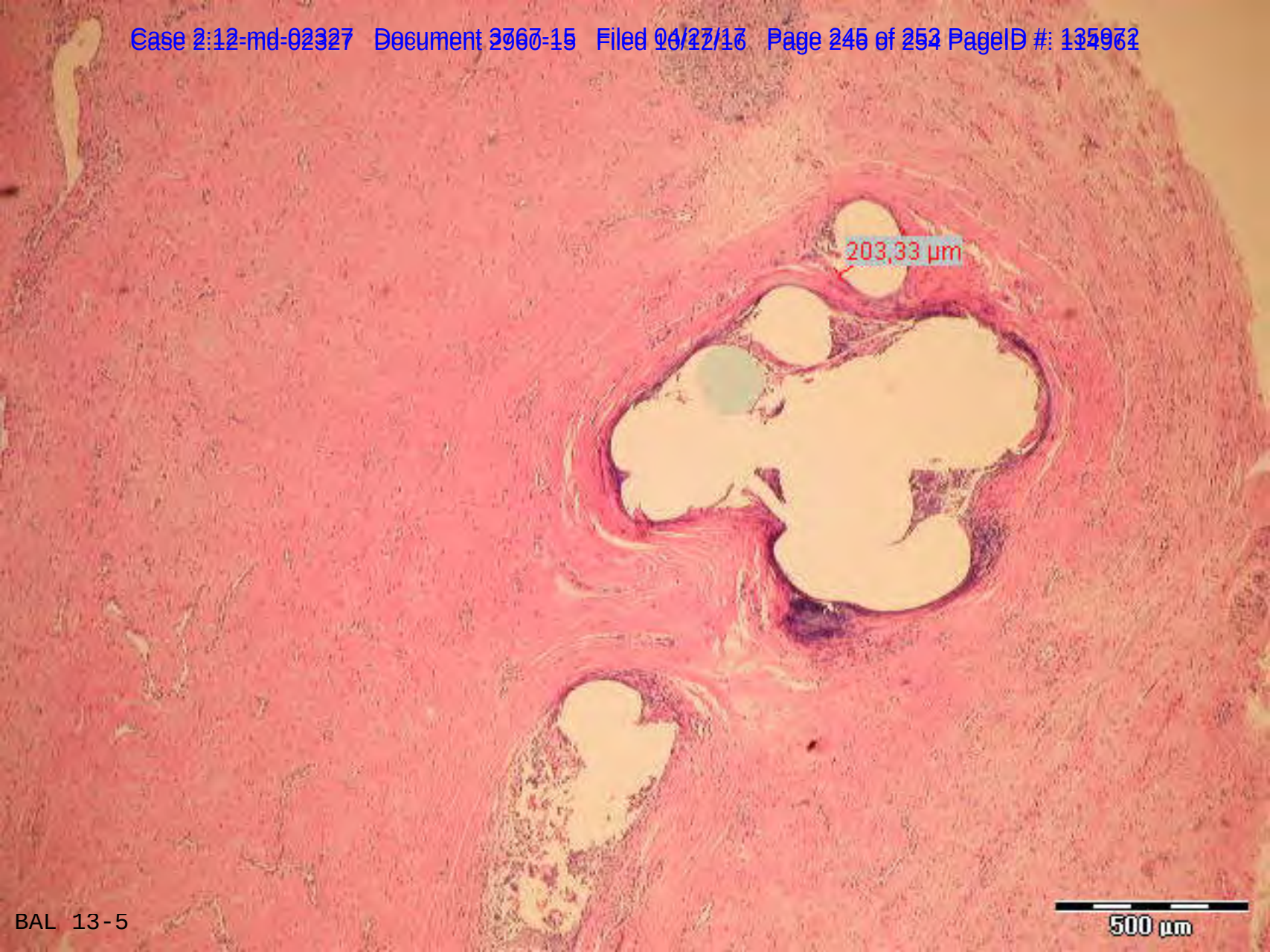
BAL 13-3


BAL 13-3
500 µm

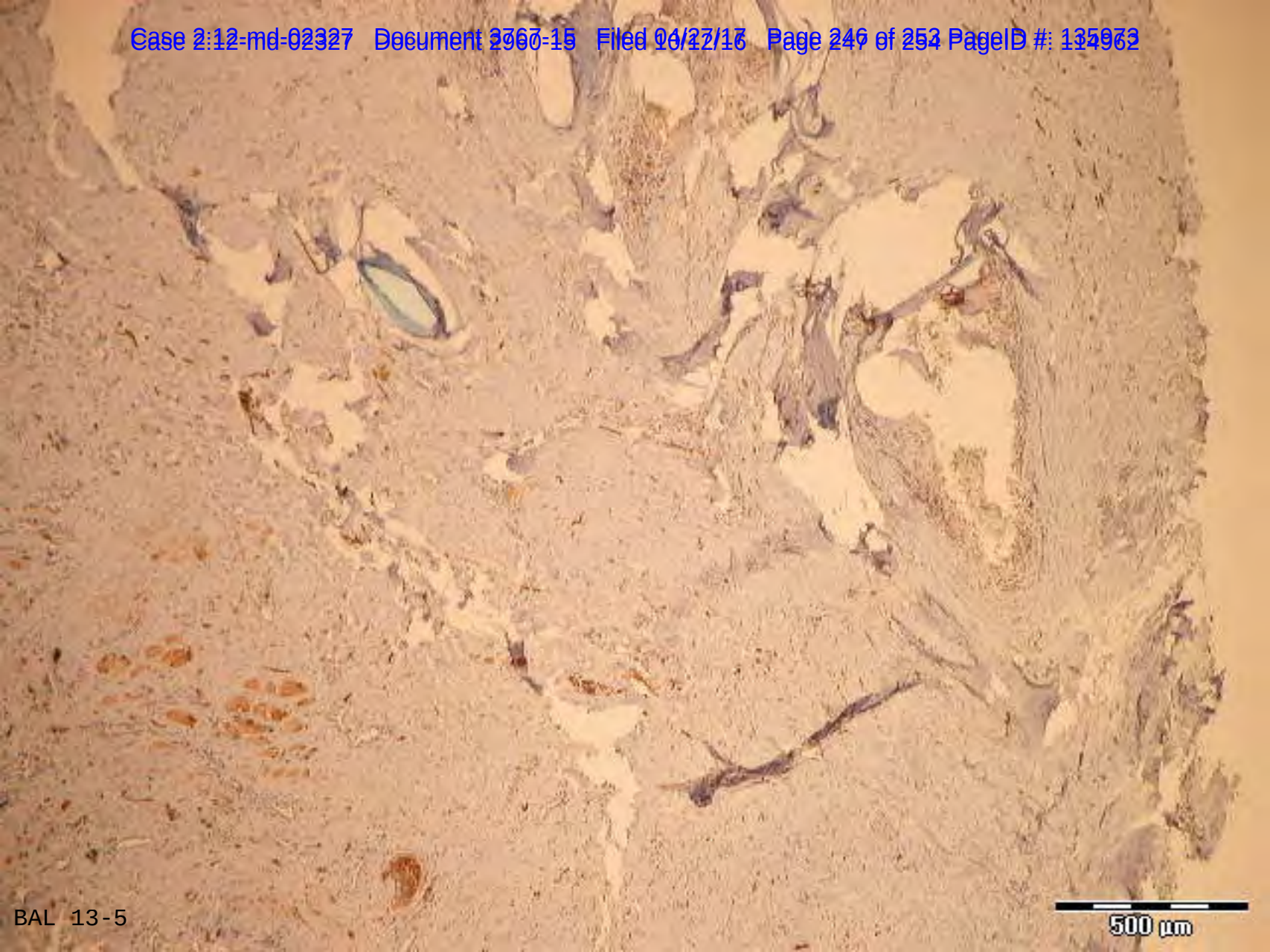

182,39 µm
500 µm
BAL 13-4

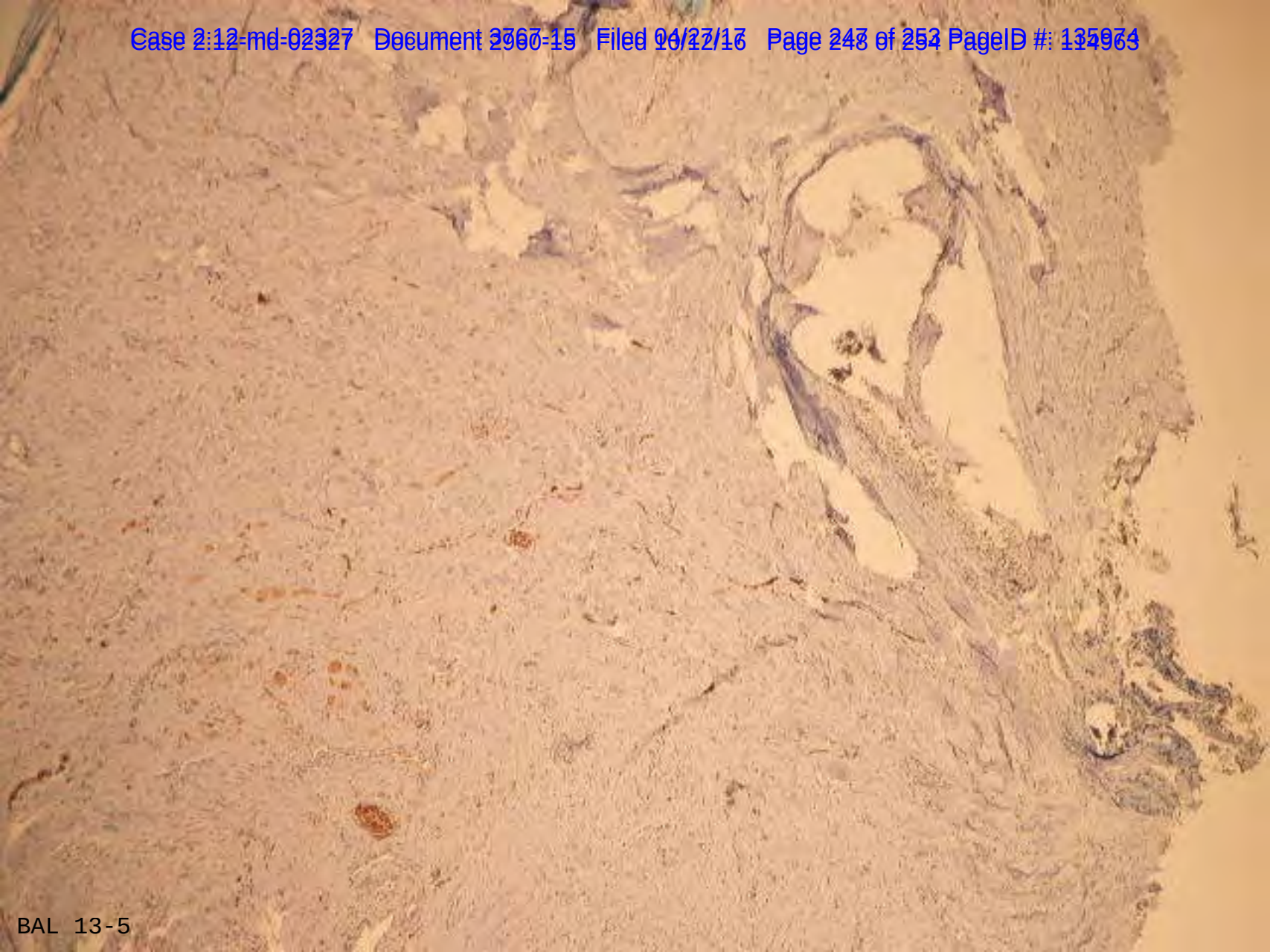


BAL 13-4

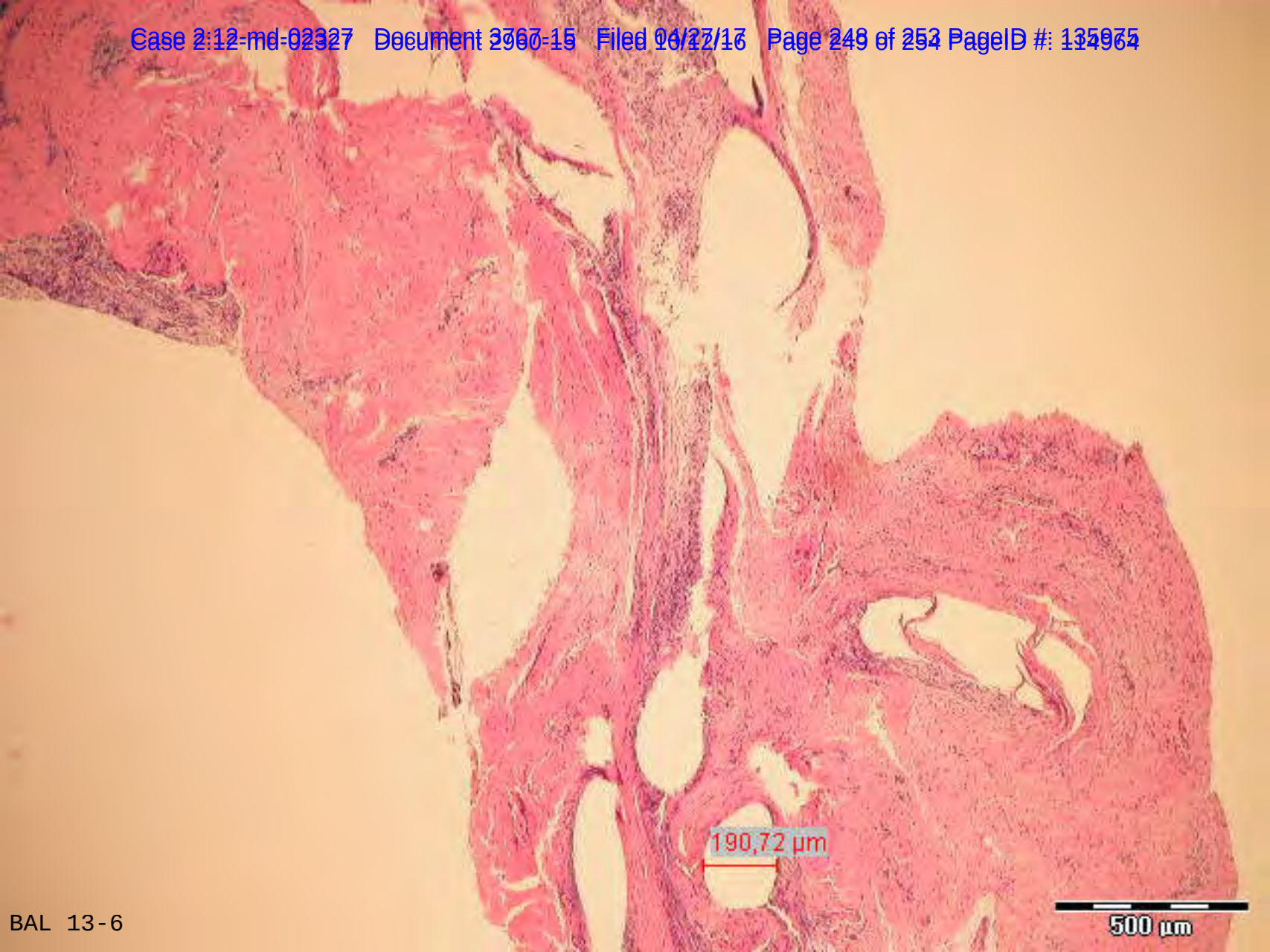


BAL 13-5

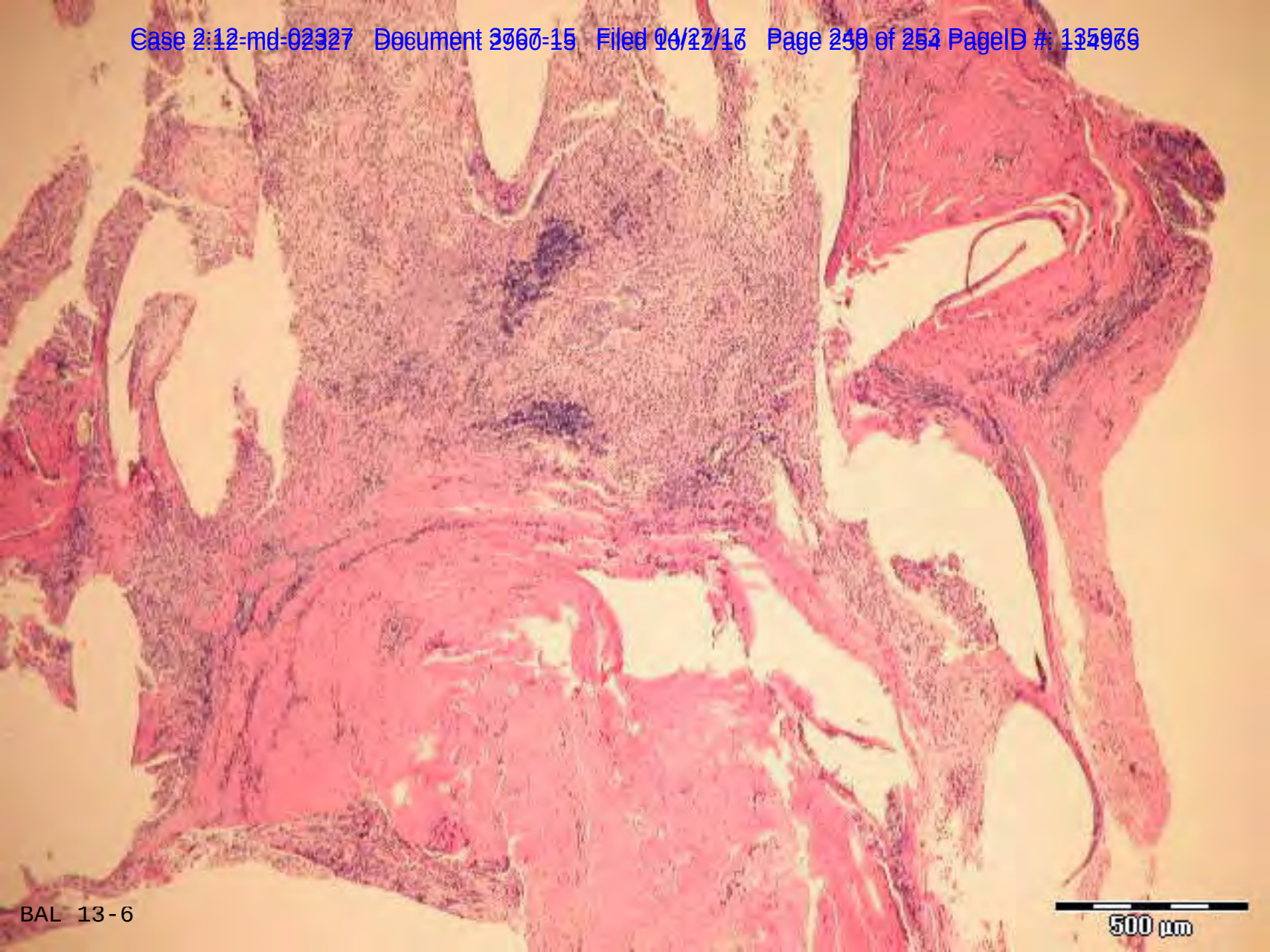

BAL 13-5
500 µm

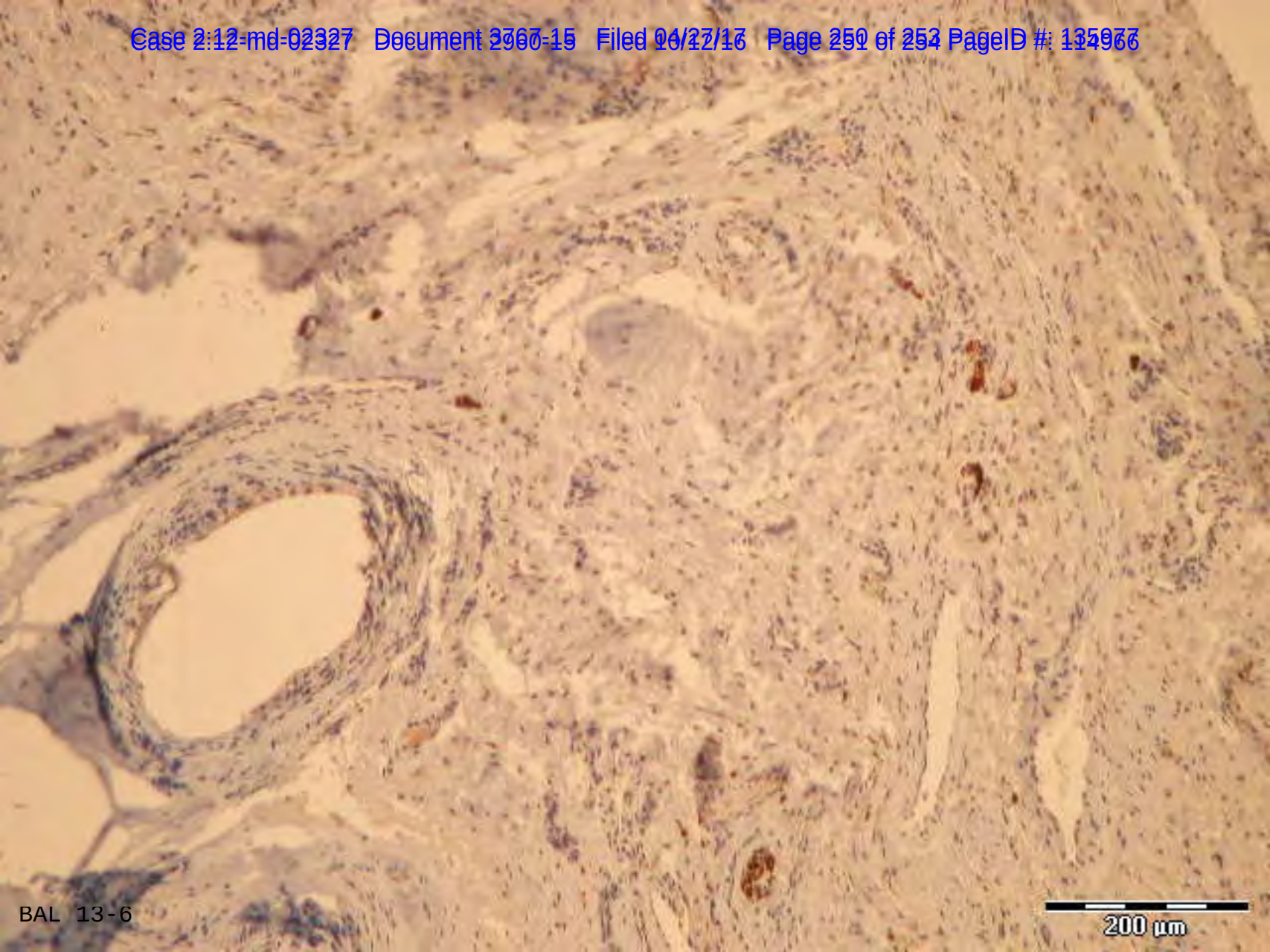


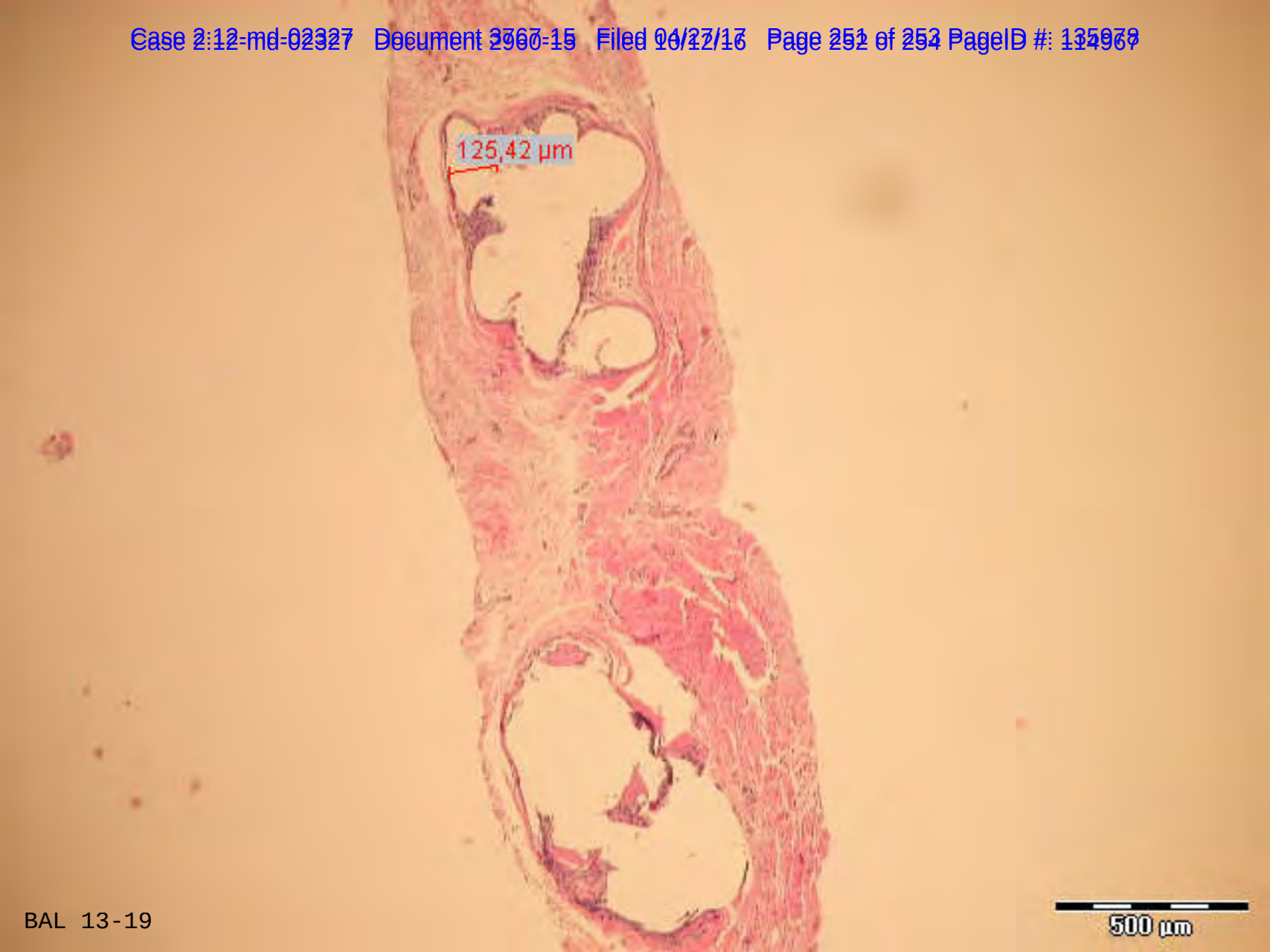
BAL 13-5



BAL 13-6


BAL 13-6
500 µm


BAL 13-6
200 µm



BAL 13-19

EXHIBIT

D

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	**Patient Name**	**DOB**	**Device**	**LCM/MCM**	**Implant Date**	**Explant Date**	**Duration of Implant (Days)**	**Reason for Explant**	**Steelgate Specimen No.**	**Jordi ID No.**	**Klinge ID No.**	**Explanting Doctor**	**Explanting Facility**	**Filament type**	**Fiber size (microns)**	**Bridging (1=<5%, 2=5-30%, 3=30-80%, 4=>80%)**	**Folding or Shrinkage (1=yes, 2=no)**	**Nerve Contact within > 1 mm of sling (1=yes, 2=no)**
2	Oiler, Jennell	12/3/1961	TVT-O	810081-MCM	1/17/2007	6/7/2012	1,968	Pain, dyspareunia	1574410- Mesh; 1706706- Tissue	13400	BAL13-9	Dr. Pulvino	Riverside Methodist Hospital	Monofilament	190	4	1	1
3	Simpson, Cynthia Ann	12/6/1964	TVT-O	810081-MCM	12/3/2009	6/7/2013	1,282	Erosion, pain, dyspareunia, bleeding	1719220- Vaginal Foreign Body	13401	BAL13-22	Dr. Matthew Oommen	Winter Haven Hospital (Outpatient)	Monofilament	136	4	1	2
4	Valentino, Gloria	1/19/1952	TVT	810041B (MCM)	10/13/2006	8/8/2012	2,126	Mesh in bladder	1594906-Tissue; 1594885- Mesh	13402	BAL13-10	Dr. Brian Rambarran MD	Niagara Falls Memorial Medical Center	Monofilament	168	4	1	2
5	Herman, Sheryl	10/2/1958	TVT	810041B-MCM	1/5/2006	8/10/2012	2,407	Extrusion of suburethral sling	0047-Mesh	13403	BAL13-11	Dr. Jae H. Kim	Advocate Christ Medical Center	Monofilament	183	4	2	1
6	Phillips, Amy Nicole	3/8/1985	TVT-O	810081-MCM	5/27/2010	11/7/2011	529	Pain, leg pain, dyspareunia	1557906- Surgical Mesh	13404	BAL13-5	Dr. John Utrie	Aurora Baycare Medical Center	Monofilament	203	4	1	1
7	Smith, Eva	7/16/1946	TVT-O	810081-MCM	11/22/2005	3/12/2012	2,302	Pain, scarring, bleeding	1573463- Mesh	13405	BAL13-4	Dr. Steven Speights	Mississippi Baptist Medical Center	Monofilament	182	4	1	1
8	Dowden, Annmarie	6/13/1971	TVT-O	810081-MCM	7/29/2008	12/28/2011	1,247		1558555-Mesh	13407	BAL13-7	Dr. Elizabeth Cruit	Baptist healthcare	Monofilament	142	4	1	1
9	Johnston-Williams, Shari	9/24/1966	TVT-O	810081-MCM	1/29/2009	12/14/2011	1,059	Erosion	1558430- Mesh; 1558429- Tissue	13408	BAL13-6	Dr. Kevin Miller	Cyprus Surgery Center	Monofilament	190	4	1	1
10	Sharp, Jacqueline	6/22/1966	TVT	810041B (MCM)	12/13/2005	3/12/2013	2,646	Erosion, pain, dyspareunia	1719047- vaginal Mesh	13409	BAL13-21		Carolinas Laboratory Network	Monofilament	141	4	1	1
11	Ioannou, Stella	12/10/1961	TVT-O	810081-MCM	4/1/2008	8/31/2011	1,247		1539514-Mesh	13410	BAL13-1		CARES SURGICENTER - St. Peter's healthcare System	Monofilament	224	4	1	1
12	McNamara, Eve	8/19/1949	TVT-O	810081-MCM	4/18/2009	9/5/2012	1,236	Erosion	0323- Mesh	13411	BAL13-12	Dr. Heather Van Raalte	Princeton Hospital	Monofilament	159	4	1	1
13	Thomas, Theresa	8/8/1968	TVT-O	810081-MCM	11/12/2009	9/14/2012	1,037	Dysuria, dyspareunia, pain, bleeding	0527- Suburethral Mesh; 0528-Tissue	13412	BAL13-13	Dr. Jerome L. Yaklic, MD	Miami Valley Hospital	Monofilament	182	4	1	2
14	Pankey, Tina	12/15/1968	TVT-O	810081-MCM	7/31/2007	9/21/2012	1,879	Infection, inflammation, erosion, pain, dyspareunia, bleeding, urin leakage	1763865- mesh	13413	BAL13-14	Dr. Holly Richter	UAB Medical	Monofilament	175	4	1	1
15	Keller, Linda	10/3/1955	TVT	810081L-LCM	8/25/2009	10/31/2012	1,163	Constipation and difficulty voiding	1957672- Mesh	13414	BAL13-15	Dr. Timothy Yoost	Three Rivers medical Center	Monofilament	156	4	1	1
16	Harden, Terri	9/8/1963	TVT	810081-MCM	3/30/2005	11/6/2012	2,778		1957836- Mesh; 1957837- Tissue	13415	BAL13-16	Dr. Carol Graham	Norton Suburban Hospital	Monofilament	154	4	1	1
17	Long, Phyllis	10/17/1954	TVT-O	810081-MCM	12/12/2004	12/13/2012	2,923	Pain, erosion, bleeding, discharge, dyspareunia, urine and fecal leakage, infections	1762577- Mesh; 1762578- Tissue	13416	BAL13-17	Dr. Barbara Robinson	Georgia health Science medical Center	Monofilament	178	4	1	2
18	Garcia, Alma	5/25/1957	TVT	810081-MCM	12/14/2010	12/21/2012	738	Pain and dyspareunia	1762880- mid urethral sling	13417	BAL13-18	Dr. Sophie Fletcher	The Methodist Hospital	Monofilament	181	4	1	2
19	Bonee, Dorothy	5/31/1942	TVT-O	810081-MCM	3/10/2006	1/11/2013	2,499	Erosion, pain, dyspareunia	1763052- mesh	13418	BAL13-19	Dr. Thomas Landon/Kelly	Summit Hospital	Monofilament	125	4	2	2
20	Robinson, Tasha	3/25/1988	TVT-O	810081L (LCM)	1/6/2009	5/22/2013	1,597	Pain	1718801- mid urethral mesh	13419	BAL13-20	Dr. Marc Ashby	Southview Medical Center	Monofilament	144	4	1	2
21	Gomez, Flor	8/12/1959	TVT-O	810081-MCM	10/8/2009	9/26/2011	718	Chronic pelvic pain, dyspareunia, perineal scar, recurrent UTIs	1539920- Mesh	13420	BAL13-2	Dr. Patricia Dramitinos	Montefiore - Einstein Hospital	Monofilament	146	4	1	1
22	Shaw, Ava	6/28/1960	TVT	810041B-MCM	3/19/2007	10/24/2011	1,680		1572618- Eroded Vaginal Sling	13421	BAL13-3	Dr. Robert Harris	Baptist Medical Center	Monofilament	167	4	1	1
23	Lewis, Carolyn	5/30/1954	TVT	810041B-MCM	1/1/2009	9/10/2013	1,713	Dyspareunia, incomplete bladder emptying, mixed incontinence	1685196 - Suburethral tape	13422	BAL13-23	Dr. Phillipe Zimmern	UT Southwestern Medical Center	Monofilament	127	4	1	1